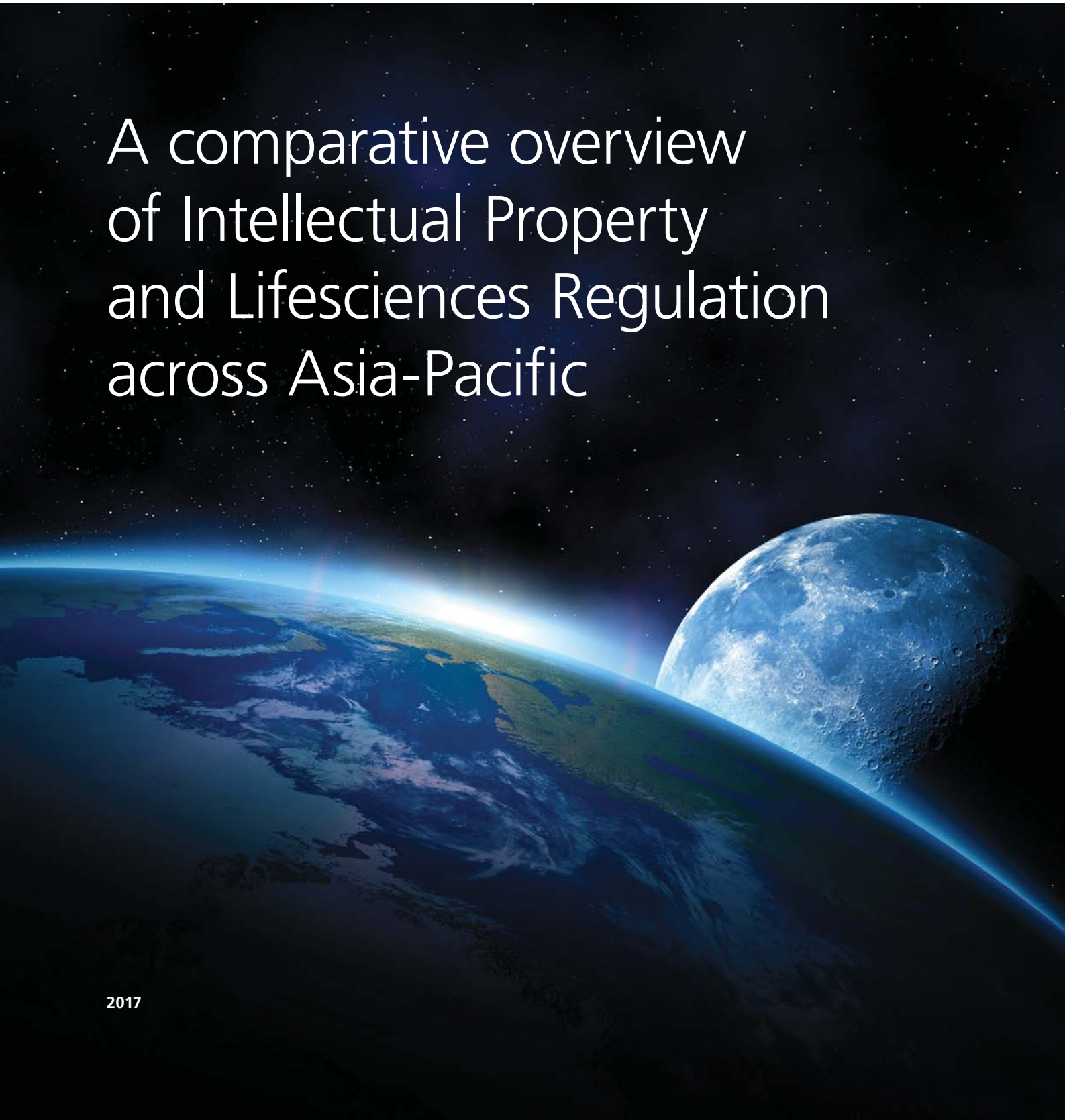
LAN
Lifesciences Asia-Pacific Network

A comparative overview of Intellectual Property and Lifesciences Regulation across Asia-Pacific



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Foreword

Lifesciences Asia-Pacific Network (LAN)

For many years, emerging markets have been strategically important for the growth and development of the Lifesciences sector. Almost 90% of the sector now operates in an emerging market, including the Asia-Pacific region.

For many Lifesciences companies, including those based in Japan, Singapore has become the regional hub, many now having offices, manufacturing sites or other bases there. We have also seen the rapid and significant growth of China to become the third largest market in the sector over the last 10 years, with the market still growing.

The opportunities available to the Lifesciences sector in Asia-Pacific are promising, but they are not without challenges and risks, particularly in IP and regulatory areas. For example, in light of the highly reported anti-bribery investigations many global pharmaceutical companies have reviewed their regulatory policies and also the distribution of registered and unregistered drugs. Many companies in the region also continue to protect and enforce their IP rights as drugs are copied and sold at reduced cost.

The Lifesciences Asia-Pacific Network (LAN) has been established for the Lifesciences sector to support and guide clients on all their legal and regulatory needs in the Asia-Pacific region, offering a highly knowledgeable 'one-stop shop'. LAN brings together nine of the leading and largest law firms in the region, including Assegaf Hamzah & Partners, Atsumi & Sakai, CMS, Chen & Lin, Corrs Chambers Westgarth, Rajah & Tann Singapore LLP, Tilleke & Gibbins and Yulchon LLC.

This guide by LAN provides a comparative overview of the regulatory and IP considerations in seven of the priority jurisdictions for the Lifesciences sector, including Australia, China, India, Indonesia, Korea, Singapore, Taiwan, Thailand and Vietnam. It also highlights the key legal and commercial issues to consider when doing business to help you maximise opportunity and minimise risk.

We hope that you find this guide helpful and informative, as you explore and continue to do business in the Asia-Pacific region.

If you would like to discuss specific issues and questions, we would be delighted to hear from you.

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Highly commended for building an Asia-Pacific Lifesciences business and network of local firms through the Lifesciences Asia-Pacific Network (LAN)

Regulatory

Australia

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**

- The *Therapeutic Goods Act* 1989 (Cth) (the **TG Act**).
- The *Therapeutic Goods Regulations 1990* (Cth) (the **TG Regulations**).
- The *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (the **Medical Devices Regulations**).
- The *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth) (the **Administration Act**).
- The *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (the **Code Act**), scheduled to which is the Agricultural and Veterinary Chemicals Code (the **Agvet Code**).
- The *Agricultural and Veterinary Chemicals Act 1994* (Cth).

— **Main Regulatory Authorities**

- The Therapeutic Goods Administration (the **TGA**), a division of the Australian Government Department of Health and Ageing, is responsible for regulating medicines and medical devices intended for human use.
- The Australian Pesticides and Veterinary Medicines Authority (the **APVMA**), is the Australian government authority responsible for regulation of agricultural and veterinary (**agvet**) chemical products up to and including the point of retail sale.

How are pharmaceuticals (human and animal) and medical devices registered for import?

— **Registration of Imported Medicines for Human Use**

- The TG Act requires that human medicines (whether prescription or over-the-counter (**OTC**)) supplied in or exported from Australia be included in the Australian Register of Therapeutic Goods (**ARTG**) unless exempt or excluded.
- Medicines can either be *registered or liste*d on the ARTG depending on the level of risk associated with the product. *Registered* medicines are considered to be higher risk than *listed* medicines. All prescription medicines and most OTC medicines are registered.
- In addition to inclusion on the ARTG, licences and permits are required to import certain narcotic drugs, psychotropic substances, precursor chemicals, antibiotics and androgenic/anabolic substances under the *Customs (Prohibited Imports)* Regul*ations 1956*.

— **Prescription Medicines for Human Use**

- An application to register a prescription medicine on the ARTG is submitted online through the TGA's eBusiness Services system and must be accompanied by a dossier (in the Common Technical Document format) which contains data that supports the quality, safety and efficacy of the product for its intended use.
- The registration process consists of eight phases, each of which has a milestone that must be completed before commencement of the following phase.

    1. Pre-submission phase – the applicant lodges a '*Pre-submission planning form*' (**PPF**) which provides information to the TGA to arrange appropriate resourcing for the processing of the application. If a PPF is considered complete and acceptable, the TGA will send a '*Planning Letter*' to the applicant identifying the expected dossier lodgement date and target milestone dates for the application.
    2. Submission phase – the applicant submits a dossier and pays any necessary fees. The TGA will then send a letter to the applicant identifying whether the application has been considered effective and accepted for evaluation. The dossier must include draft Product Information and Consumer Medicine Information.
    3. First round assessment phase – the TGA assesses data in the dossier, and sends a '*consolidated section 31 request*' (where there are questions or issues about the application) and copies of the first round assessment reports.
    4. Consolidated section 31 request response phase – the applicant responds to the request and the first round assessment reports (if necessary).
    5. Second round assessment phase – the TGA assesses the applicant's response to the section 31 request and issues second round assessment reports.
    6. Expert advisory review phase – a Delegate of the Secretary to the Department of Health (the **Delegate**) considers the assessment reports and if necessary, seeks advice from the Advisory Committee on Prescription Medicines (**ACPM**) or other subcommittees. The TGA will then notify the applicant of the advice received from the ACPM.
    7. Decision phase – the Delegate determines whether the application is to be approved or rejected and sends a letter outlining this decision to the applicant.
    8. Post-decision phase – the TGA completes any administrative and regulatory activities and finalises outstanding payments and the ARTG entry.

- The TGA has developed the Australian Regulatory Guidelines for Prescription Medicines (**ARGPM**) to provide information on the requirements of registering prescription medicines on the ARTG.

— **OTC Medicines for Human Use**

— Registration of an OTC Medicine

- Applications to register an OTC medicine are categorised into five levels based on risk. Lower risk levels include applications to register OTC medicines that contain well-understood active ingredients or that are identical to existing OTC medicines (i.e. generics). Higher risk levels include more complex applications such as medicines with new active ingredients or new indications. Less supporting information is required and shorter turnaround times apply to lower risk level applications.
- An application to register an OTC medicine is submitted online through the TGA's e-Business Services system and needs to be accompanied by:
    1. a dossier which includes data that supports the safety, quality and efficacy of the product;
    2. copies of all labelling; and
    3. copies of draft Product Information and Consumer Medicine Information.
- During the evaluation process, the TGA may make requests for further information to address outstanding issues before a decision is made by the Delegate as to whether the medicine should be registered on the ARTG.
- The TGA has developed the Australian Regulatory Guidelines for OTC Medicines (**ARGOM**) to provide further information on the requirements of registering OTC medicines on the ARTG.

— Listing of an OTC Medicine

- An application to list an OTC medicine is submitted online through the TGA's e-Business Services system and is subject to less scrutiny than an application to register an OTC medicine. In particular, therapeutic indications on listed medicines are not evaluated by the TGA at the time of listing. Nevertheless, the TG Act requires that, at the time of listing, sponsors certify that they hold evidence to support indications and claims made and that this information be made available to the TGA upon request.
- The TGA has developed the Australian Regulatory Guidelines for Complementary Medicines (**ARGCM**) to provide further information on the requirements of listing OTC medicines on the ARTG.

— **Veterinary Medicines**

- The Agvet Code requires that an agvet chemical, including a veterinary medicine, that is manufactured, imported, supplied, sold or used in Australia be registered with APVMA. An application is made online through the APVMA portal.

— **Registration of Imported Medical Devices**

- The TG Act requires medical devices imported into, supplied in, or exported from Australia to be included on the ARTG (unless exempt or excluded).
- An application for inclusion on the ARTG is submitted online through the TGA's e-Business Services system and can be made if the medical device complies with the '*Essential Principles*' and appropriate conformity assessment procedures have been applied to the device.
- Medical devices are classified depending on the manufacturer's intended use of the device; the level of risk to patients, users and other persons; the degree of invasiveness in the human body; and the duration of use. The classification levels are:
    1. *Class I* – Low risk
    2. *Class I (supplied sterile)* – Low to medium risk
    3. *Class I (incorporating a measuring function)* – Low to medium risk;
    4. *Class IIa* – Low to medium risk
    5. *Class IIb* – Medium to high risk
    6. *Class III* – High risk
    7. *Active implantable medical devices* (AIMD) – High risk
- The TGA has developed the Australian Regulatory Guidelines for Medical Devices (**ARGMD**) to provide further information on the requirements of including a medical device on the ARTG.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

- The TG Act requires that manufacturers of human medicines and medical devices hold a licence and makes it an offence to manufacture such goods without a licence unless the manufacturer or the goods are otherwise exempt.
- Examples of exempt goods include homeopathic remedies and extemporaneous preparations.
- Examples of exempt persons are doctors and pharmacists manufacturing in the usual practice of their professions.

— **Human Medicines**
- The *Therapeutic Goods (Manufacturing Principles)* Determination No 1 (2013) requires that medicinal products supplied in Australia must meet the '*PIC/S Guide to Good Manufacturing Practice - 15 January 2009, PE 009-8*' except for Annexes 4, 5 and 14 which are not adopted by Australia.

— **Veterinary Medicines**
- All veterinary chemical products must be manufactured in premises that comply with the '*Code of Good Manufacturing Practice*' unless the product is excluded or exempt (such as listed or reserved products or products like skin cleansers, shampoos or sheep branding substances).
- Australian facilities must be licensed by APVMA, or hold a permit, and overseas manufacturers must provide equivalent evidence of compliance at the time of application for registration of products.

— **Medical Devices**
- Manufacturing medical devices in Australia for the Australian market – Australian manufacturers of Class I Sterile, Class I Measuring, Class IIa, Class IIb, Class III and AIMD medical devices are required to hold a TGA Conformity Assessment Certificate before applying for inclusion onto the ARTG.
- Manufacturing medical devices in Australia for export to overseas markets – Manufacturers wishing to apply for an export only medical device need to have the device included on the ARTG as a Class I medical device.
- Manufacturing medical devices overseas for import into the Australian market – a TGA Conformity Assessment Certificate is required for the following manufacturers before the medical device can be included on the ARTG and supplied into the Australian market:
    1. all Australian manufacturers (except those manufacturing only Class 1 non-sterile or non-measuring devices);
    2. any manufacturer who manufactures medical devices containing materials with animal, microbial or recombinant origin;
    3. any manufacturer who manufactures medical devices containing medicinal substances (that is, substances that if used separately would be considered medicines);
    4. any manufacturer who manufactures medical devices containing derivatives of human blood or plasma.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— **Medicines for Human Use**
- As noted in Section A2, above, a medicine for human use must be either registered or listed on the ARTG before it can be supplied in Australia, unless exempt or otherwise authorised by the TGA. Restrictions on marketing of medicines for human use are discussed in Sections B and F below.

— **Veterinary Medicines**
- As noted in Section A2, above, a veterinary medicine sold in Australia must be registered with APVMA.

— **Medical Devices**
- As noted in Section A2, above, a medical device supplied in Australia must be included on the ARTG. Restrictions on marketing of medical devices are discussed in Sections B and F below.

Advertising

What are the restrictions on advertising medicinal products?

— **Restrictions concerning drugs**
- OTC drugs can generally be advertised to the general public (unless the drug is a pharmacist-only product).
- Prescription-only and certain pharmacist-only drugs are prohibited from being advertised to the general public and may only be promoted to health professionals.

— **Restrictions concerning advertisements for drugs**
- Any promotion of prescription drugs to health professionals in Australia must comply with the Medicines Australia Code of Conduct which creates standards for the ethical marketing and promotion of drugs.
- Consumer facing advertisements for OTC drugs must comply with the following requirements:
    1. Each advertisement must comply with the requirements of the Therapeutic Goods Advertising Code.
    2. Prior approval from the Australian Self Medication Industry is required for advertisements appearing in broadcast media, print media (including in newspapers and magazines), outdoor or display advertising (including billboards) or advertisements appearing in a cinema film. For complementary medicines, prior approval must be obtained from Complementary Medicines Australia.
    3. Approved advertisements will receive a unique approval number. This number must be appear in the advertisement.
    4. Prior approval is not required for advertisements that appear in other advertising formats (such as e-mails and on adverting on internet sites).
    5. In general, advertisements must not be directed towards minors.
    6. Advertisements must not be capable of misleading or confusing a consumer as to the proper use or identification of the product.
    7. Advertisements must not refer to the TGA, use a government logo, or imply that any government body (including a foreign government agency such as the FDA) endorses or has approved the product.
    8. In general, advertisements must not contain representations about a drug that causes abortions or a drug that treats tumours, sexually transmitted diseases, HIV AIDS and/or HCV or mental illnesses.
- Drugs (including prescription-only drugs) must not be advertised or promoted for indications other than the indications for which they have been accepted into the ARTG.

— **Restrictions concerning medical devices**
- Medical devices may be advertised to the general public.

— **Restrictions concerning advertisements for medical devices**
- The regulatory requirements are similar to those applying to consumer facing advertising for OTC drugs except that there is no requirement to seek prior approval.

Packaging and labelling

The regulation of the packaging and labelling of medicinal products

— **Regulations concerning drug packaging**
There are two main requirements concerning the packaging of drugs:

- Subject to certain limited exemptions, the packaging for drugs must be child-resistant. Therapeutic Goods Order 80 sets out the requirements for child-resistant packaging.
- The TGA encourages products to be packaged in tamper evident packaging in accordance with the Code of Practice for the Tamper-Evident Packaging of Therapeutic Goods.

— **Regulations concerning labelling of drug products**

- Therapeutic Goods Order No. 69 regulates the information that must be displayed on the label of a drug.
- The information that must be displayed on a product drug includes:
  (a) the product name;
  (b) the name(s) of all active ingredients and their quantity (using metric units of measurement);
  (c) in some cases, information about ingredients other than active ingredients;
  (d) relevant warning/advisory statements (including as required under the Poisons Standard and the Required Advisory Statements for Medicine Labels);
  (e) expiry dates;
  (f) directions for use;
  (g) storage conditions;
  (h) name and address of the sponsor or supplier of the product;
  (i) in most cases, the indications for which the product can be used; and
  (j) the ARTG registration number (for drugs listed on the ARTG).
- This information must in English and in durable, legible lettering that is not less than 1.5mm in height (except for the ARTG registration number which can be 1mm high).

— **Regulations concerning medical devices packaging**

- The Medical Devices Regulations impose a number of requirements on the packaging of medical devices including:
  (a) the product must be packaged in a way that is suitable for its purposes as a medical device;
  (b) the product's characteristics and performance must not be adversely affected during its transport or storage;
  (c) the packaging must minimise the risk of the introduction of contaminants; and
  (d) the device must remain sterile or be easily sterilised.

— **Regulations concerning labelling of medical devices**

- Medical Devices Regulations prescribe the information that must be included on a medical device itself or, if that is not possible, on the packing for the device. This information includes:
  (a) information identifying the device (including batch code, lot or serial number);
  (b) information identifying the manufacturer and sponsor of the device (including name and address); and
  (c) information explaining how to use the device safely (including information about handling and storage requirements, the intended purpose and users of the device, warnings, restrictions and precautions and operating instructions).
- This information must in English and in legible lettering that is not less than 1mm in height.
- The Therapeutic Goods Order No. 37 sets out additional requirements which apply for different kinds of packaging.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system, and how is it funded?

- The Australian national healthcare system consists of both private and public run enterprises. Public sector health providers include public hospitals and community and public health services which provide population screening and immunisation services. Private sector health service providers include private hospitals, pathology service providers, medical practices and pharmacies.
- Expenditure on the Australian national health care system is predominantly funded by the Government (approximately 70%). The remaining 30% is paid for by a combination of patients, private health insurers and accident compensation schemes.

How are the prices of medicinal products regulated?

— **Pharmaceuticals**

- Australia maintains a Pharmaceutical Benefits Scheme (**PBS**) under which the government subsidises the price of certain medicines. The price is adjusted in line with inflation.
- The Pharmaceutical Benefits Advisory Committee (**PBAC**) advises the Australian Government as to whether a medicine should be available on the PBS. The price that the government pays to the supplier of the medicine is negotiated between the Pricing Section of the Department of Health and the supplier of the medicine.
- Private (non-PBS) medicines are not subsidised by the Australian Government and prices are determined by market forces.

— **Regulations for the pricing of medical devices**

- In public hospitals, medical devices are purchased following competitive tender processes and are provided free of charge for patient use. By contrast, in private hospitals, medical devices are purchased by private hospitals/hospital groups with categories of devices reimbursed via contractual arrangements with health funds (e.g. procedure banding or the Prostheses List, discussed below).

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— **Medicines**

- Medicines listed on the PBS are available to patients at Government-subsidised prices. The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement (**RHCA**) are also eligible to access the PBS. Australia currently has RHCAs with the United Kingdom, Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands, Finland, Norway, Belgium and Slovenia.

— **Medical Devices**

- Compared to medicines, reimbursement of medical devices is complex and occurs in different forms depending on whether a patient is in the public or private health system.
- For medical devices which are implantable (prostheses) in the *public* health system, for patients in public hospitals, the cost is covered by the Government.
- Eligibility for reimbursement of implantable medical devices within the *private* health insurance system is assessed by the Prostheses List Advisory Committee (**PLAC**). The PLAC advises the government on the listing of prostheses in the '*Prostheses List*' and the appropriate benefits for which a private health insurer is required to pay for such prostheses when provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service. Products on the Prostheses List include cardiac pacemakers, cardiac stents and hip replacements.
- There are a number of federal schemes providing medical aids and appliances in Australia at subsidised prices including the Repatriation Pharmaceutical Benefits Scheme and the National Diabetes Services Scheme.

Clinical trials

For clinical trials of drugs

- All clinical trials conducted in Australia must have a 'sponsor' who is an Australian individual, company or organisation. The sponsor is responsible for ensuring that the trial is conducted in accordance with applicable regulatory requirements. Sponsors must have a client ID, issued by the TGA.
- There are two schemes under which clinical trials of unapproved drugs may be conducted in Australia: the Clinical Trial Notification (**CTN**) scheme and the Clinical Trial Exemption (**CTX**) scheme.
- The decision as to which scheme to use is ultimately a decision for the sponsor of the trial together with the applicable Human Rights Ethics Committee (**HREC**). A determining factor is usually whether the HREC has appropriate scientific and technical expertise to assess the safety of a drug without involving the TGA.
- Under the CTN scheme:
    1. information and data relating to a proposed clinical trial (including the trial protocol) is submitted to the HREC for review. The HREC assesses the scientific validity, safety, efficacy and ethical acceptability of the trial; and
    2. the trial is notified to the TGA and the appropriate notification fee paid however the TGA does not review any data relating to the trial.
- Under the CTX scheme:
    1. the sponsor of a clinical trial submits an application to conduct clinical trials to the TGA for evaluation and comment;
    2. a delegate of the TGA reviews the information and decides whether or not to raise an objection. If an objection is raised, the trial cannot proceed until the objection has been resolved to the delegate's satisfaction;
    3. the sponsor must forward any comments from the TGA delegate to the sites where a clinical trial will be conducted;
    4. a sponsor can commence a clinical trial once written advice has been received from the TGA regarding the CTX application and approval for the conduct of the trial has been obtained from a HREC and the site where the trial will be conducted; and
    5. a sponsor can conduct any number of clinical trials under the CTX application provided that these fall within the scope of the TGA approval.

For clinical trials of medical devices

- Clinical trials of medical devices can be conducted under the CTN or CTX schemes (as described above). Clinical trials of medical devices also require an Australian sponsor.

Restrictions on dealing with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

- The marketing practices of pharmaceutical and medical device companies are largely the subject of self-regulation by various industry bodies. For example, restrictions on marketing practices are imposed by Codes of Conduct administered by:

    1. Medicines Australia (which represents innovator pharmaceutical companies);
    2. the Generic and Biosimilars Medicines Association (which represents generic pharmaceutical companies); and
    3. the Medical Technology Association of Australia (which represents the medical devices industry).

  Breaching these codes of conduct can result in significant monetary sanctions, especially for repeat offenders.

- In some instances, member companies of these industry groups are required to publicly make available details of speaking fees, advisory board fees or sponsorships to attend a conference made to individual healthcare professionals.

- In addition to industry Codes of Conduct, professional codes of conduct for medical practitioners such as the Australian Medical Board's Code of Conduct provides that '*good medical practice*' involves avoiding dealings which may affect or be seen to affect the way a medical practitioner prescribes for, treats or refers patients. Although such professional codes of conduct are not legislation per se, they are admissible in disciplinary proceedings against a health practitioner as evidence of what constitutes appropriate professional conduct.

Reform

Are there proposals for reform and when are they likely to come into force?
In July 2015 the Expert Panel Review of Medicines and Medical Devices Regulation delivered its report to the government. The report made 58 recommendations for reform of the sector. These recommendations included:

- that new pathways for registration on the ARTG of new chemical entities, generics, and complementary medicines be put in place, including an accelerated provisional registration to be supplemented after registration by further data demonstrating safety, quality, and efficacy;
- that the TGA work more closely with National Regulatory Authorities in other countries, such as registering substances that have obtained regulatory approval in other countries, subject to minor conditions;
- that the Government review the range of products on the ARTG under the medicines framework to determine whether products might be best regulated under other regulatory frameworks;
- that the Government undertake a comprehensive review and re-draft the *Therapeutic Goods Act* with an aim to:
  - improve transparency and user friendliness;
  - provide flexibility for the TGA to modify processes;
  - regulate medicines and medical devices differently; and
  - provide graduated penalties for minor to serious non-compliance
- that the TGA develop more comprehensive post-market monitoring of listed medicinal products; and
- that future requirements for advertising therapeutic products are made consistent for medicines and medical devices, and that the process of vetting and pre-approving advertisements be replaced with a self-regulatory regime.

The Government is yet to provide a response to these recommendations, so it is unlikely that any of them will come into force in the near future.

China

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**
- The Drug Administration Law

— **Main Regulatory Authorities**
- The China Food and Drug Administration ('CFDA')

How are pharmaceuticals (human and animal) and medical devices registered for import?

— **For Registration of Imported Pharmaceuticals**
- Applicants file clinical trial applications with the CFDA which will approve the clinical trial application after review. Following completion of the clinical trial, the applicant files a marketing authorisation application with the CFDA which will issue an Import Drug Licence.

— **For Registration of Imported Medical Devices**
- There are three classifications of medical device (I, II, & III).
- For Class I Imported Medical Devices, applicants submit records for filing to the CFDA.
- For Class II and Class III Imported Medical Devices, applicants obtain a medical device test report from a testing institution and then conduct a clinical trial. The applicant files a medical device registration application to the CFDA which will issue an Import Medical Device Licence after examination.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

Only manufacturers can obtain a Drug Licence or Medical Device Licence which represents the required approvals for both manufacturing and marketing.

— **For Pharmaceutical Registration**
— New Drug Registration
  - The applicant files a clinical trial application to the Provincial Food and Drug Administration ('FDA');
  - The Provincial FDA and CFDA will review and approve the clinical trial;
  - Following completion of the clinical trial, the applicant should file a marketing authorisation application with the Provincial FDA. The Provincial FDA and CFDA will review and issue a Drug Licence.

— Generic Drug Registration
  - Generic Drug Registration is similar to New Drug Registration.

— **For Medical Device Registration**
  There are three classifications of medical device (I, II, & III).
  - **For Class I Medical Devices:**
    – The applicant should submit records for filing to the Provincial FDA.
  - **For Class II Medical Devices:**
    – Similar to the procedure for Imported Medical Device Registration. Please see above. The only difference is the applicant should file the application to the Provincial FDA.
  - **For Class III Medical Devices:**
    – Same as the procedure for Imported Medical Device Registration. Please see above.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— In China, marketing and manufacturing are covered by the same Drug Licence or Medical Device Licence.

— For an outline of the applicable drug and medical device marketing registration procedures, please see above.

Advertising

What are the restrictions on advertising medicinal products?

— Restrictions on advertising medicinal products can be divided into restrictions concerning products and restrictions concerning advertisements themselves.

— **Restrictions concerning drugs**

- It is strictly forbidden to make advertisements for anaesthetics, psychotropic drugs, toxic drugs and radioactive drugs.
- Formulations prepared by medical institutions, drugs that do not have a Drug Licence and drugs specifically required by the army may not be advertised.

— **Restrictions concerning advertisements for drugs**

- Adverts must include the general name of the drug, information, drug advertisement licence number and drug production licence number, and the name of the manufacturing or trading enterprise.
- The information provided should be true and in accordance with the law and the approved registration information. The advert must not contain any information that is false, unscientific, or a categorical assertion or warranty of any described function.
- Adverts for non-prescription drugs shall be specifically indicated as non-prescription drugs (OTC). Adverts for prescription drugs should indicate that the drugs are only being offered to doctors and pharmacists.

— **Restrictions concerning medical devices**

- Adverts for specific devices are forbidden by the CFDA. Adverts for devices for internal use are prohibited.

— **Restrictions concerning advertisements for medical devices**

- Adverts must contain the name of the approved medical device, the name of the manufacturing enterprise, registration certificate number and advertisement licence number.
- All information shall conform to the product certificate issued by the CFDA.
- Medical devices may be freely advertised to adults but may not target children. Adverts must not be published in child publications, media channels, programmes or columns.

Packaging and labelling

The regulation of the packaging and labelling of medicinal products

— **Regulations concerning drug packaging**

- Drug packaging must conform to the common standards of human health and safety, as well as strictly complying with the 'National Standards for Drug Packaging'.
- Only packaging approved by the CFDA can be used. Packaging applications are submitted together with the application for drug approval. Different procedures apply depending on whether the application is for domestically manufactured packaging or imported packaging.
- Penalties: confiscation of products and all revenues; fines; revocation of drug licence, drug manufacturing licence or drug trading licence; criminal procedures and sanctions etc.

— **Regulations concerning labelling of drug products**

- Labels must contain as a minimum: the drug name, applications or functions of the drug, specifications, usage and dosage, production date, product batch number, use-by date and manufacturing enterprise etc.
- Any expression used on a label must be scientific, standardised and accurate. Expressions used for OTC drugs must be drafted in plain and simple language that can be understood by consumers.
- The wording of labels should not be obscured by means of affixation, cutting or alteration.
- Penalties: administrative penalties; revocation of the drug licence and criminal procedures and sanctions.

— **Regulations concerning medical devices packaging**

- To date, there are no specific rules regulating the packaging of medical devices.

— **Regulations concerning labelling of medical devices**

- Legal rules applicable to labels for medical devices are similar to those applicable to labels for drugs - please see above.
- For sterilised or disposable medical devices, labelling should include wording or marks of precaution, such as 'sterilised' or 'disposable use'; the sterilisation method and the method by which to deal with any damaged sterilisation package; appropriate method of disinfection or sterilisation that should be adhered to prior to the use of the medical device.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system, and how is it funded?

— The majority of hospitals in China are state-owned, but with the economy developing, and government encouragement, more private hospitals are being established.

— Basic Medical Insurance and Rural Cooperative Medical Insurance is provided and funded by the Chinese Government and covers almost the whole country. Both insurances have reimbursement lists (Provincial Catalogue) which differ according to Province.

— Commercial health insurance is very popular and is being encouraged by the government.

How are the prices of medicinal products regulated?

The National Development and Reform Commission ('NDRC') and the Provincial DRCs set the price of medical products.

— **Drug pricing regime**

- Government pricing approach - The authorities use the average production cost of all manufacturers in the industry to calculate the Government retail price. The NDRC publishes and updates a catalogue of drugs that are subject to Government pricing regulations.
- Market pricing - based on production or operation costs and market supply and demand.

— **Regulations for the pricing of medical devices**

- The Government sets few regulations on medical device pricing. Manufacturers can usually set prices independently.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— State funded insurance will provide reimbursement at point of sale.

— Commercial insurance will reimburse products after the patient has paid.

Clinical trials

The clinical trial procedures

— **For clinical trials of drugs**

- After the approval of the clinical trial, the Sponsor should select the institution and report to CFDA. The Sponsor signs a clinical trial agreement with the investigator and establishes an Ethics Committee which will issue an approval.
- The Sponsor submits documentation to the CFDA and Provincial FDA.
- The Investigator conducts the clinical trial and the sponsor reports the results to the CFDA.

— **For clinical trials of medical devices**

- The procedures for medical devices are similar to those for drugs - please see above.

Restrictions on dealings with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— Compared to Western countries, the anti-bribery system is relatively simple. Providing gifts, sponsoring, or consultancy for benefit could constitute a crime which may lead to fines and confiscation of all illegal income; revocation of business licence, drug manufacturing licence, drug trading licence and criminal prosecution etc.

— Sponsorship may only be made in the public interest and must not be profit-making and not linked with the sale of medical products.

— Companies found guilty of bribery will be listed on a 'blacklist' from which hospitals and clinics are not allowed to purchase.

Reform

Are there proposals for reform and when are they likely to come into force?

— Recently, the Chinese government agreed to implement a Pharmaceuticals Market Authorisation Holder ('MAH') regime in 10 pilot areas where research institutions and individuals would be expected to be qualified as a Pharmaceutical MAH.

— The Chinese government has been reducing its control over drug prices since May 2015. Negotiation and bidding mechanisms will be widely used in setting drug prices. However, a detailed implementation scheme is still under discussion.

— The government will unify Basic Medical Insurance and Rural Cooperative Medical Insurance into a national insurance scheme in the coming years.

India

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals?

— **Main Legislation**

- The Drugs and Cosmetics Act, 1940 ('**DC Act**') and the Drugs and Cosmetics Rules, 1945 ('**DC Rules**');
- The Essential Commodities Act, 1955;
- The Drug (Prices Control) Order, 2013 ('**DPCO**');
- The Legal Metrology Act, 2009;
- The Pharmacy Act, 1948;
- The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 ('**Drugs and Magic Remedies Act**');
- The Drugs (Control) Act, 1950 ('**Drugs Control Act**')
- The Narcotic Drugs and Psychotropic Substances Act, 1985;
- Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988;
- Medicinal and Toilet Preparations (Excise Duties) Act, 1955;
- Bureau of Indian Standards Act, 1986 ('**BIS**') and certain relevant orders passed by the Central Government under it; and
- Relevant state-level legislation.

— **Main Regulatory Authorities**

- Department of Pharmaceuticals, Ministry of Chemical & Fertilizers;
- Ministry of Health and Family Welfare.
- Ministry of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy;
- Indian Council of Medical Research ('**ICMR**')
- National Pharmaceutical Pricing Authority;
- Central Drugs Standard Control Organisation ('**CDSCO**');
- Drug Controller General of India ('**DCGI**');
- State Drug Control Authorities; and
- Central Drugs Laboratory.

How are pharmaceuticals (human and animal) and medical devices registered for import?

— Pharmaceuticals cannot be imported without an import licence.
— Different import licences are issued depending upon the purpose of such import.
— The DC Act and DC Rules regulate the import, manufacture and marketing of Pharmaceuticals (human and animal) and medical devices.
— The DC Act and DC Rules specify the standard, quality and purity of drugs for import, manufacture, sale and distribution.
— Drugs which are not of a standard quality, or are 'misbranded' drugs, 'adulterated' drugs and 'spurious' drugs, cannot be imported, manufactured, sold, stocked, exhibited or offered for sale.
— A manufacturer who has a valid wholesale licence for sale or distribution of drugs is also required to apply for a registration certificate for the importation of the drugs. This involves the manufacturing facility being inspected and registered.
— The grant of the import licence is subject to continued compliance by the manufacturer and the licencee with specified conditions.
— The import licence may be suspended or cancelled if the manufacturer or licencee fails to comply with these conditions.
— The notified medical devices by the Central Government are considered as 'drugs' under the DC Act and DC Rules. All the requirements for registration and licensing under the DC Act and DC Rules as applicable to drugs are applicable to notified medical devices.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

— Depending upon the type of drug, different kinds of licences are required for the manufacture or distribution of drugs.
— The DC Rules provide for requirements and standards to be followed by factory premises for the manufacture of medical devices in Schedule M – III which has been recently amended to include specific requirements for a quality management system.
— The medical devices are also required to adhere with the standards laid down by BIS wherever prescribed.
— 'New drugs' have to be approved by the DCGI.
— 'New drugs', i.e., those drugs being used for claims other than those already approved, or drugs that have not been used for any significant extent under the conditions prescribed, or fixed dose combinations, etc., are regarded as 'new drugs' and have to be approved by the DCGI
— Once approved by the DCGI, a licence to manufacture or distribute will be issued by the DCGI.
— After the expiry of four years, the licence to manufacture and distribute these drugs can be issued by the state.
— Therefore, marketing approval for 'new drugs' must be obtained prior to obtaining manufacturing licences.

As set out above, these provisions also apply to certain notified medical devices that are treated as drugs under the DC Act and DC Rules.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— Drugs apart from new drugs can be marketed upon procuring an import license or manufacturing license (as applicable) and a wholesale/retail license from the State Government(s) in question.
— New drugs, on the other hand, require approval of the CDSCO. The application process for marketing is intertwined with the licensing required to manufacture or import the new drug (as applicable).

Advertising

— The Drugs and Magic Remedies Act prohibits the advertisement of certain drugs for certain specified diseases. The Drugs and Magic Remedies Act defines advertisement to include any notice, circular, label, wrapper or other document and any announcement made orally or by any means of producing light, sound or smoke.

— Under the Drugs and Magic Remedies Act, no person is allowed to advertise any drugs which suggests or are calculated to the use of the drug for:

  - Procurement of miscarriage or prevention of conception in women;
  - Maintenance or improvement of the capacity of humans for sexual pleasure;
  - Correction of menstrual disorder in women; and
  - Any other disease or treatment which may be specified in the schedule or rules made thereunder. Some of the diseases specified in schedule of Drugs and Magic Remedies Act include cancer, cataracts, epilepsy, leprosy and obesity.

— Misleading advertisements relating to drugs which give a false impression about the drugs are also prohibited under the Drugs and Magic Remedies Act.

— The prohibition does not apply to:

  - any signboard or notice displayed by a registered medical practitioner including the treatment for any disease;
  - any treaties or book dealing with any of the matters from a bona fide scientific standpoint;
  - any advertisement related to any drug sent confidentially to any registered medical practitioners or to chemists for distribution among registered medical practitioners or to a hospital or laboratory; and
  - Government advertisements.

— Further, as per recent amendment to the DC Rules, the conditions of certain licenses have been amended to prohibit advertisement of Schedule X, H and H1 drugs (commonly referred to as prescription drugs) without prior Central Government sanction.

— In addition to the legislative restriction stated above, the Central Government has also published a Uniform Code of Pharmaceuticals Marketing Practices ('Uniform Code'), a voluntary code which was to be adopted and complied with by the pharmaceutical industry for a period of six months commencing from 1 January 2015. The validity of the Uniform Code was increased repeatedly vide multiple notifications till June 30, 2016 and it is currently applicable till any further orders are passed in this regard.

— The Uniform Code provides that a drug must not be promoted prior to receipt of marketing approval from the competent authority authorising its sale and supply. The Uniform Code also provides for the manner of promotion of a drug, e.g. usage of word 'safe' shall not be used without qualification or the word 'new' should not be used for a drug that has been generally available in India or if its therapeutic indication has been generally promoted for more than 12 months.

— Further, the Organization of Pharmaceutical Producers of India ('OPPI') has also released a 'Code of Pharmaceutical Practices' that sets out certain advertising-related standards. However, this is only applicable to those pharmaceutical companies which are a member of OPPI.

— Also, the Indian advertising self-regulatory body, the Advertising Standards Council of India, has developed a general code for setting advertising standards around the central theme of honest advertising.

Packaging and labelling

The regulation of the packaging and labelling of medicinal products.

— The DC Act and DC Rules contain various regulations relating to the labelling and packaging of different classes of drugs including drugs to be exported and drugs to be sold within the country

— The labels for drugs to be exported should be adapted to meet requirements of the importing country but the following must be mentioned therein:

- the name of the drug;
- the name and address of the manufacturer;
- licence number; batch or lot number; and
- date of expiry.

— The description of the dosage varies depending on the kind of drug and form of administration. The prescription drugs should be labelled as such and appropriate warning should be displayed i.e. concerning whether the drug is for internal use, external use, etc.

— These requirements can be adapted to meet the requirements of an exporting country in the case of imports.

— Export regulations in certain cases (e.g. for narcotic and psychotropic drugs) permit that the labelling could exclude the name and address of the manufacturer, but instead it should bear a code number issued by the licensing authorities in addition to other specified conditions

— The Rules separately provide for labelling requirements for medical devices through an amendment in 2014 under Rule 109A. Certain exemptions are granted to those medical devices manufactured for export.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system, and how is it funded?

— The nodal agencies responsible for the healthcare system in India are the Ministry of Health & Family Welfare ('**Health Ministry**') and the Ministry of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy respectively, being wings of the Central Government.

— The Health Ministry operates certain schemes and programmes such as:

- **National Rural Health Mission:** Launched in 2005, this programme targets the poor, primarily rural population by providing universal access to equitable and affordable healthcare;
- **National Programme for the Health Care of the Elderly:** Launched in 2011, this aims at providing easy access to primary healthcare to the elderly population, funded by the Health Ministry;
- **Integrated Child Development Services:** Focuses on alleviating malnutrition in young children under the age of six by providing better nutrition, funded by the Government, UNICEF and the World Bank;
- Separately, special schemes are in operation that aim at provide affordable healthcare to Government employees such as the Central Government Health Scheme.

— Health insurance is still nascent and the following schemes are currently in operation:

- **Rashtriya Swasthya Bima Yojana:** Launched in 2009, this scheme targets health insurance for people who are living below the poverty line and is financed by both the Central and the State Governments.
- **Employees State Insurance Scheme:** This is financed by the State Governments, the employers and the employees and covers employees below a specified income threshold.

— The above schemes are financed in a variety of means as we have discussed above.

How are the prices of medicinal products regulated?

The Drug Price Control Order, 2013 ('**Price Control Order**') regulates the prices of drugs in India.

- The Price Control Order provides a mechanism for calculation of the ceiling price for a scheduled formulations and new drugs. The Price Control Order also provides a mechanism for calculating the maximum retail prices for the drugs which includes the sum of ceiling prices and local taxes. The maximum retail prices are set by the manufacturers on the basis of retail prices determined by the Government.
- The Government also revises the ceiling prices of scheduled formulations as per the annual wholesale price index for the preceding calendar year on or before 1 April of every year and notifies of the same on this date. The manufacturers may increase the maximum retail price of scheduled formulations (including the national list of essential medicines published by Central Government) once in a year, in the month of April, without the prior permission of the Government, on the basis of the wholesale index relating to the previous year.
- The Price Control Order also gives wide powers to the Government to fix the price of any drug in extraordinary circumstances and for such period as it thinks fit.
- The Government under the Price Control Order is mandated to monitor the prices of non-scheduled formations and all the drugs ensuring that manufacturers do not increase the maximum retail price of a drug more than 10% during the preceding 12 months. When the increase is more than 10% the manufacture shall reduce the same to the level of 10% of the maximum retail price for the next 12 months. In such event, the manufacturer shall be liable to deposit the overcharged amount along with the interest and penalty with the Government.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

- There is no general provision under the medical laws in India for reimbursement for medical expenses by the Government to the patients. Although, under different health schemes formulated by Central or State Government, the patients may be eligible for subsidised medicines and treatment expenses, depending on the criteria of the scheme (such as, only for the patients below the poverty line).
- In certain cases, Government employees (both Central & State Government) are entitled to reimbursement of medical expenses under the medical insurance coverage policy or any departmental rules applicable to such Government employees.

Clinical trials

— The DC Act and DC Rules contain various provisions regulating the conduct of clinical trials.

— New clinical trials require prior approval from the central licensing authority.

— Registration of trials in the Clinical Trial Registry ('CTR') maintained by the ICMR is required.

— Detailed rules exist in relation to the conduct of clinical trials including reporting, informed consent, and compensation.

— The CDSCO has clarified that the same procedure shall be followed for medical devices as well. However, medical devices shall be exempt from Phase I of the clinical trial procedure

Restrictions on dealings with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— The conduct of pharmaceutical companies or their medical representatives are subject to the voluntary Uniform Code mentioned above.

— Under the Uniform Code the pharmaceutical companies or their agents are not allowed to give any gifts, pecuniary advantages, or benefits in kind to persons qualified to prescribe or supply drugs.

— Even gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) such as tickets to entertainment events are not allowed.

— Further, healthcare professionals that are public servants under Prevention of Corruption Act, 1998 ('PCA') are prohibited from receiving any gratification, other than legal remuneration, as a motive or reward for doing or refraining from doing any official act or favouring or disfavouring any particular person, as well as any attempt or agreement thereof. 'Gratification' under the PCA is not limited to mere pecuniary gratification or any kind of gratification estimable in money.

Reform

Are there proposals for reform and when are they likely to come into force?

The following policy initiatives are being planned by the Central Government:

— Amendments in the DC Act for the upgrade and introduction of provisions for clinical trials and regulation of medical devices.

— Amendments in the DC Rules in the light of new provisions to be incorporated under the DC Act, and strengthening of rules relating to quality control of drugs, cosmetics and medical devices.

— Simplification and rationalisation of various formats of applications and licences under the DC Rules.

— Revision of Good Manufacturing Practices for drugs as well as medical devices under the DC Rules, to update the requirements to make them on par with the international requirements.

— Amendment to the Drugs and Magic Remedies Act.

— Publication of a revised national list of essential medicines and essential devices

— Finalisation of accreditation standards for ethics committee, investigator and clinical trials.

— Evolving of Public Private Partnership model for engaging laboratories in the private sector.

— Reforms to the packaging standards with respect to exporting drugs.

— Drafting of Medical Devices Regulation Act is underway

— The government has also proposed setting up business parks for the manufacture of medical devices providing them with the required infrastructure.

Indonesia

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**

- Law No. 7 of 1963 on Pharmacy
- Law No. 36 of 2009 on Health
- Regulation of the Minister of Health No. 1010/Menkes/Per/XI/2008 as amended by No. 1120/Menkes/Per/XII/2008 on Drug Registration ('**RMOH 1010/2008 as amended**')
- Regulation of the Head of National Agency of Drugs and Food Control No. HK.03.1.23.10.11.08481 on the Criteria and Guidelines of Drug Registration

— **Main Regulatory Authorities**

- The Ministry of Health
- The National Agency of Drugs and Food Control / *Badan Pengawas Obat dan Makanan* ('**BPOM**')

How are pharmaceuticals (human and animal) and medical devices registered for import?

— For Registration of Imported Pharmaceuticals

- Registration documents are to be submitted to the BPOM together with the official fee. An imported medicine needs to be registered by a domestic pharmaceutical producer that has obtained written approval from the foreign pharmaceutical producer. The written approval must provide for a transfer of technology so that the drug can be produced locally within a five-year period, except if it is patented. The foreign pharmaceutical producer must also comply with Good Drug Manufacturing Practices/*Cara Pembuatan Obat Yang Baik* ('**CPOB**'), as evidenced by relevant documents or an inspection by the Indonesian authorities. The documents must be attached to the application, together with the latest data on inspections conducted by the relevant local authorities (that is, for at least the last two years). The BPOM either approves or rejects the application for Marketing Authorization/Izin Edar based on the recommendation of the committees. If the registration is rejected, the applicant is allowed to submit a request for re-examination.

— For Registration of Imported Medical Devices

- Any medical devices to be distributed in Indonesia must obtain Marketing Authorization/*Izin Edar*. The registration documents to obtain Marketing Authorization/*Izin Edar* are to be submitted to the Ministry of Health together with the official fee. The application for Marketing Authorization/*Izin Edar* of an imported medical device is to be submitted by:

  a. The medical device distributor in possession of a license as a sole agent of the type of product and acknowledged by the local representative in the Republic of Indonesia, with an appointment term of minimum 2 (two) years;

  b. The medical device distributor, if not a sole agent, should possess the power of attorney to register the medical device from the medical device manufacturer overseas;

  c. The company in possession of the production certificate to carry out the reassembling / repacking of imported products.

  The imported medical devices to be registered should be accompanied by (i) a letter which certifies that the medical devices have been marketed and used in the country of origin of the products or in other countries, and (ii) other documents that show the safety or quality of the medical devices from the competent government agency according to the needs in the evaluation process.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

— For Pharmaceutical Registration

- The manufacture of drugs may only be conducted by a pharmaceutical industry company which has obtained a Pharmaceutical Industrial License from the Ministry of Health.
- The pharmaceutical industry company must comply with the CPOB. Fulfilment of the CPOB is evidenced by a CPOB certificate issued by the Head of BPOM, which will be valid for a period of 5 years.
- In addition to compliance with CPOB, a pharmaceutical industry company is obliged to conduct pharmacovigilance in accordance with the prevailing BPOM regulation.

— For Medical Device Registration

- The manufacture of medical devices may only be conducted by a company which has obtained a Production Certificate issued by the Ministry of Health.
- A company which manufactures medical devices shall be responsible for the quality and safety of its medical devices.
- Such company is required to comply with Good Medical Device Manufacturing Practices/*Cara Pembuatan Alat Kesehatan yang Baik* ('**CPAKB**') which is determined by the Ministry of Health.
- The government will monitor and evaluate compliance with CPAKB at least once a year.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— **For Pharmaceutical Registration**

Pursuant to RMOH 1010/2008 as amended and the Regulation of the Head of BPOM No. HK.03.1.23.10.11.08481 on the Criteria and Guidelines of Drug Registration, any drugs to be distributed within the Indonesian territory shall be firstly registered to obtain Marketing Authorization / *Izin Edar*.

The application to obtain Marketing Authorization / *Izin Edar* must be submitted to BPOM as the government body which has the authority to conduct evaluation and assessment on drugs that will be distributed in Indonesia.

— **For Medical Device Registration**

Similar to the pharmaceutical regime, any medical devices to be marketed in Indonesia shall be firstly registered to obtain Marketing Authorization / *Izin Edar*. However, the Marketing Authorization / *Izin Edar* for medical devices is issued by the Ministry of Health.

Medical devices that obtain Marketing Authorization / *Izin Edar* should comply with the following criteria:

a. The safety and efficacy of medical devices, which are proven by conducting clinical tests and/or other evidences that are needed;

b. The quality, which is assessed from good manufacturing practices and using materials with appropriate specifications and comply with determined requirements.

What are the restrictions on advertising medicinal products?

— A company intending to advertise medical products must obtain an advertising license from the BPOM.

— Further, according to the prevailing regulations, medical product advertising shall not:

- promote excessive and continuous use of the medical products;
- provide misleading and inaccurate information about the medical products;
- use children as advertising models without adult supervision;
- describe that children may decide to use and choose such medical products;
- be played by health professionals or actors acting as health professionals by using health professional attributes;
- give recommendation by referring to statements made by health professionals (e.g. 'my doctor recommends to use this drug');
- provide guarantee about the efficacy of the medical products.

The regulation of the packaging and labelling of medicinal products

— According to BPOM regulations, the following information shall be included in the labelling of medical products:

- Name of medical products;
- Packaging dimensions;
- Ingredients of medical products;
- Name and address of the person to whom the product is to be registered;
- Name and address of the producer;
- Name and address of the license provider;
- Marketing Authorization/*Izin Edar* number;
- Production date;
- Expiry date;
- Side effects;
- Indications;
- Warnings (e.g. must be accompanied with prescription from a doctor).

— Labelling of medical products must be provided in Bahasa Indonesia. Nevertheless, other languages may be used as long as there are no equivalent words in Bahasa Indonesia.

What is the structure of the national healthcare system, and how is it funded?

— **Structure of the National Healthcare System**

- Healthcare effort
- Health research and development
- Health funding
- Human resources in healthcare sector
- Provision of pharmaceuticals, medical devices, and food
- Health management, information, and regulations
- Community development.

— **How is it funded?**

— Mixed financing system

- The Government and individuals share the burden of financing the national healthcare system.

How are the prices of medicinal products regulated?

— The government determines the Highest Retail Price / *Harga Eceran Tertinggi* ('HET') for 2 (two) types of drugs, namely generic drugs and brand name drugs.

— The HET for generic drugs is determined annually by the Ministry of Health.

— As for brand name drugs, the HET is determined by the formula of Pharmacist Nett Price / *Harga Netto Apotek* ('**HNA**') + 28% of HNA

— HNA is the selling price (including value added tax) from a Large Pharmacist Distributor to a pharmacist, drug store, or hospital pharmacy.

— A pharmacy or drug store is prohibited to sell drugs above the HET determined by the government.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— The Government, through its social security programs, subsidises medical treatment, medication and hospital bills depending on the social-economic situation of an individual.

— The Ministry of Health maintains a generic drug list which lists drugs that have been determined to be essential to the provision of basic health care, and the prices of these drugs are therefore kept at an affordable level.

The clinical trial procedures

— Any person who intends to conduct a clinical trial must obtain approval from the BPOM. The approval shall be valid for 2 years since the issuance date.

— The clinical trial must comply with the principles of Good Clinical Trial Practices / *Cara Uji Klinik Yang Baik* determined by the BPOM.

— The product that will be used in the clinical trial shall have initial safety data and quality requirements in accordance with its clinical trial stage.

— The sponsor providing funding for the clinical trial shall report the side effects of the product to the BPOM at the latest 15 calendar days since the side effect was first recorded.

— The sponsor is obliged to submit several reports to the BPOM, among others:

- A semester report (every 6 months);
- A report at the completion of the clinical trial, at the latest 30 business days after the completion date;
- If the clinical trial is terminated prior to completion, a report at the latest 15 business days after the termination date.

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Any gifts in the form of money (cash, loan, voucher, ticket, etc.) provided by the pharmaceutical industry or a large pharmaceutical distributor / *pedagang besar farmasi* to health care professionals who prescribe their drugs are not allowed.

Are there proposals for reform and when are they likely to come into force?

— None at the moment.

Japan

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in Japan?

— **Main Legislation**

- The Act regarding Ensuring Quality, Effect and Safety of Pharmaceuticals and Medical Device, etc. (the Act on Pharmaceuticals and Medical Devices; formerly the Pharmaceutical Affairs Act, hereinafter, the "Act"), which regulates pharmaceuticals, quasi-drugs, cosmetics, medical devices and tissue-engineered medical products in order to ensure certain quality, effectivity and safety levels are maintained.

— **Main Regulatory Authorities**

- Ministry of Health, Labour and Welfare (MHLW) for pharmaceuticals for human use and medical devices
- Ministry of Agriculture, Forestry and Fisheries (MAFF) for pharmaceuticals for animal use

How are pharmaceuticals (human and animal) and medical devices registered for import?

1. **Pharmaceuticals for Human Use**
   - A foreign manufacturer may obtain approval to manufacture pharmaceuticals for export to Japan, and the Minister for MHLW may grant an approval for each manufactory.
2. **Medical Devices**
   - A foreign manufacturer may be registered by the Minister for MHLW to manufacture and to export medical devices to Japan, and the Minister of MHLW may grant a registration for each manufacturing plant.
3. **Pharmaceuticals for Animal Use**
   - The Act requires approval from the Minister of MAFF in order to import pharmaceuticals for animal use. This requirement is waived if the pharmaceutical for animal use is imported only for research purposes.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

— **Pharmaceuticals for Human Use**

- Only manufacturers permitted by the Minister for HMLW may manufacture pharmaceuticals for human use specified in accordance with the Act. There are two kinds of pharmaceuticals for human use (class 1 for prescription drugs and class 2 for over-the-counter drugs) and the requirements for permission vary depending on which category the pharmaceuticals fall into. Permission must be renewed within a certain period designated by MHLW ordinance. Prescription drugs require approval by MHLW based on reliability evaluation and approval examination conducted by the Pharmaceuticals and Medical Devices Agency. Over-the-counter drugs generally require MHLW approval based on equivalency evaluation and approval examination conducted by the Pharmaceuticals and Medical Devices Agency; however, some kinds of medicines including cold medicines and antipyretic analgesics (including NSAIDs and other painkillers) require approval from each governor of the prefecture in which it is to be sold.

— **Medical Devices**

- Only manufacturers registered by the Minister for HMLW may manufacture the medical devices specified in accordance with the Act. Previously, under the former Pharmaceutical Affairs Act, the manufacture of each medical device required permission from the Minister for HMLW. However, considering the short life cycle of medical devices, this system was simplified to a manufacturer registration system instead. Registration shall be renewed within a certain period designated by the MHLW ordinance.

  In addition, a manufacturer of medical devices shall have its factory registered by the Minister for MHLW. A business manufacturer of medical devices must provide (i) its name and address, (ii) address of factory, and (iii) matters described by MHLW in order to be registered. In addition, registration as a business manufacturer must be renewed within a certain period designated by MHLW ordinance.

— **Pharmaceuticals for Animal Use**

- Only manufacturers permitted by the Minister for MAFF may manufacture pharmaceuticals for animal use specified in accordance with the Act.

How are pharmaceuticals (human and animals) and medical devices registered for marketing?

— **Pharmaceuticals for Human Use**

- Only persons (including companies) permitted by the Minister for HMLW may market pharmaceuticals for human use specified in accordance with the Act. This permission for marketing is provided in conjunction with approval for manufacturing.

— **Medical Devices**

- Only persons (including companies) permitted by the Minister for HMLW may market the medical devices specified in accordance with the Act. This permission for marketing includes permission to market medical devices.

  The three kinds of specified medical devices are:

  1. Class 1 for medical devices requiring high-level controls, meaning medical devices for which the potential risk to human life and health is significant in the event of a malfunction or in terms of their side effects;
  2. Class 2 for medical devices requiring controls, meaning medical devices which pose a potential risk to human life and health in the event of a malfunction or in terms of their side effects; and
  3. Class 3 for general medical devices, meaning medical devices for which the potential risk to human life and health is insignificant in the event of a malfunction or in terms of their side effects.

  Requirements for permission vary depending on the kind of medical devices. Approval for Class 1 and some Class 2 medical devices requires examination by the Pharmaceuticals and Medical Devices Agency. Approval for other Class 2 medical devices requires certification by a third party certification institute, while Class 3 medical devices only require self-certification. Permits must be renewed within a certain period designated by MHLW ordinance.

— **Pharmaceuticals for Animal Use**

- Only manufacturers permitted by the Minister for MAFF may manufacture pharmaceuticals for human use specified in accordance with the Act.

Advertising

Advertising in Japan is regulated under a number of statutes, including the Act against Unjustifiable Premiums and Misleading Representations (AUPMR) and other legislation and guidelines in respect of specified industries. There are also "fair commission codes", which are a set of voluntary rules prepared by trade associations in particular industries, including the pharmaceutical drug industry (by the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry), the pharmaceutical drug wholesales industry, and the alcohol beverage industry, etc. in accordance with the AUPMR in order to standardize expressions in advertising appropriate for each industry. Since each fair commission code is authorized by the Minister for the Consumer Affairs Agency (CAA) and the Fair Trade Committee, a member company which follows the relevant fair commission code is highly unlikely to be censured for infringement of the AUPMR.

For the pharmaceutical industry, the complement of the fair commission code is the Limitation on Provision of Gifts in the Pharmaceutical, Medical Device and Sanitary Laboratory Industries (No. 54 of Announcement by Fair Trade Committee, 1997).

What are the restrictions on advertising medical products?

— The Act on Pharmaceuticals and Medical Devices prohibits false or exaggerated advertising in relation to the name, effect or efficiency of medicines, quasi-drugs (whose effect on the human body is milder than drugs), and cosmetics, medical equipment and regenerative medical products; advertising that misleads consumers into thinking that a doctor guarantees the effect or efficiency of a medicine, quasi-drug, cosmetic or medical equipment; and suggests abortion or uses obscene documents or images in relation to medicines, quasi-drugs, cosmetics or medical equipment.

Packaging and Labeling

Packaging and Labeling have an advertisement feature therefore the regulation on advertising described above shall be applied. In addition, there is legislation which regulates packaging and labeling of products for provision of the necessary or important information and for risk avoidance.

Regulation of the packaging and labeling of medical products

— The Act, which specifies the label, information and design of the container, packaging or package inserts, such as specific characters and color, or the name of manufacturer, volume, efficacy and other notifications, method of listing or the matters prohibited from entry. This specification under the Act differs according to the type of products, specifically poisonous and deleterious substances, pharmaceuticals, quasi-drugs, cosmetics, medical devices and tissue-engineered medical products.

— Pharmacists Act, which specifies the label, information and design of the container or package of the medicine dispensed by pharmacist.

— Medical Practitioners' Act, which specifies the label, information and design of the container or package of the medicine dispensed by medical practitioners.

— Japanese Pharmacopoeia (JP), which is established and published to regulate the properties and quality of drugs by the Minister of MHLW after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC). The JP consists of general notices, general rules for crude drugs, general rules for preparation, general tests, processes and apparatus and official monographs.

Pricing, State Funding and Reimbursement

What is the structure of the national healthcare system, and how is it funded?

— The Japanese national healthcare system covers all residents within the national health insurance system, permits individuals to use the medical institution (such as clinics and hospitals) of their choice. It is administered under a social insurance system, and provides public money to maintain national insurance for all.

— The proportion of medical expenses borne by the individual ranges from 10% to 30% depending on age (10% for 75 and older, 20% for 70 to 74 and also 6 and younger, and 30% for ages 6 to 69). In addition, some local governments give financial assistance to children who are under certain ages (such as 15 years old) and many children can be seen by doctors for substantially free.

How are the prices of medical products regulated?

— The price of prescription medicine for human use and certain kinds of medical devices is officially set by the Minister of MHLW in accordance with the Health Insurance Act. Prices at which these are purchased by hospitals and medical institutes in practice will differ from the official prices, however, and MHLW surveys actual prices periodically and amends the official prices.

Clinical Trials

Clinical trials are conducted in accordance with the international quality standard known as Good Clinical Practice (GCP). Contract Research Organizations (CROs) report to MHLW on clinical trial plans agreed with doctors who conduct clinical trials, and MHLW reviews these plans and requires amendment if necessary. The details of clinical trials are investigated by an institutional review board (IRB) which is established for clinical trials. IRBs should be registered with the Pharmaceuticals and Medical Devises Agency (PMDA) in accordance with a notice issued by MHLW.

Institutions which conduct clinical trials must (i) have adequate medical devices and devices for inspection, (ii) have a sufficient number of doctors, pharmacists, nurses and medical staff, (iii) be able to use IRB, and (iv) take necessary countermeasures immediately in the event of an emergency.

CRO reports to MHLW on any serious unforeseen side effects.

Restrictions on Dealings with Healthcare Professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— Marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners in Japan are restricted through voluntary guidelines, including (i) Regarding the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions by the Japan Pharmaceutical Manufacturers Association (JPMA) and (ii) Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations by the Japan Federation of Medical Devices Associations (JFMDA).

Reform

Are there proposals for reform and when are they likely to come into force?

— No.

Korea

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals?

— **Main Legislation**

- The Pharmaceutical Affairs Act and Subsidiary Legislation
  - The Regulations for Safety of Drugs
  - The Standards for Manufacturers and Importers of Pharmaceuticals
  - The Standards for Facilities of Manufacturers and Importers of Pharmaceuticals
  - The Legislation on Relief for Adverse Effects of Drugs
  - The Regulations for Manufacturing and Marketing of Biological Products
  - The Standards for Animal Pharmacies and Facilities of Manufacturing, Importing and Marketing of Animal Pharmaceuticals
  - The Regulations for Handling Animal Pharmaceuticals
- The Medical Services Act
- The Act on Testing and Inspection in the Food and Drug Industry
- The Narcotics Control Act
- The National Health Insurance Act
- The Monopoly Regulation and Fair Trade Act
- The Improper Solicitation and Graft Act ('**SGA**')

— **Main Regulatory Authorities**

- Ministry of Food and Drug Safety ('**MFDS**')
- Ministry of Health and Welfare ('**MOHW**')
- Health Insurance Review & Assessment Service
- National Health Insurance Service ('**NHIS**')

How are pharmaceuticals (human and animal) and medical devices registered for import?

— **For Pharmaceuticals**

- A person, who intends to engage in the business of importing drugs, must file a report on importation business with the Minister of MFDS and obtain a marketing approval from, or file a marketing notification with, the Minister of MFDS for each product depending on the classification of such product under the Regulations for Safety of Drugs.
- Notwithstanding the first paragraph, if a person, who has filed a report on importation business, intends to import drug substances to manufacture drugs or the drugs prescribed by ordinance of the Prime Minister, including drugs for clinical trials, he or she may import drugs without obtaining a marketing approval, or filing a marketing notification for each product.

— **For Medical Devices**

- A person, who has obtained an import business approval for medical devices from the Minister of MFDS, is required to obtain an import approval or import certification, or file an import notification with regard to the medical device that he or she intends to import depending upon the classification of such medical device under the Medical Devices Act.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

— **For Pharmaceuticals**

- A person who intends to manufacture drugs for business purposes must obtain an approval from the Minister of MFDS after being equipped with the necessary facilities that satisfy the Standards for Facilities of Manufacturers and Importers of Pharmaceuticals.

— **For Medical Devices**

- A person who intends to engage in the business of manufacturing medical devices must obtain a manufacturing business approval from the Minister of MFDS and also obtain a manufacturing approval or manufacturing certification, or file a manufacturing notification depending on the classification of the medical device he or she intends to manufacture under the Medical Devices Act.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— **For Pharmaceuticals**

- In general, only pharmacy owners, licensed herb druggists and drug wholesalers are allowed to sell or obtain drugs for the purpose of sale.
- A person who has obtained a marketing approval for drugs or an importer who has filed a report on importation business may sell drugs manufactured or imported to another person who is allowed to manufacture or sell drugs under the Pharmaceutical Affairs Act.

— **For Medical Devices**

- A person who intends to engage in the business of distributing medical devices or a person who intends to engage in the business of leasing medical devices is required to file a notification of his or her distribution business or leasing business with a government authority that has jurisdiction over his or her place of business.
- The notification of the first paragraph will not be required where (i) a manufacturer or importer of medical devices distributes or leases medical devices manufactured or imported by him/her to a medical device handler, (ii) a person who has filed his or her distribution business notification engages in a leasing business, (iii) where a person who has established a pharmacy or a drug wholesaler distributes or leases medical devices, or (iv) where a person distributes medical devices for the control of contraception or medical devices used for self-diagnosis to be used at places other than medical institutions.

Advertising

— **Restrictions concerning drugs**

- Under the Pharmaceutical Affairs Act, only drugs for which market approval has been obtained can be advertised in South Korea. Advertising unapproved drugs can subject the advertising company to criminal and administrative sanctions.
- Advertisements that use false, misleading or exaggerated expressions regarding a product's effect or efficacy are prohibited. Article 68 of the Pharmaceutical Affairs Act stipulates the following advertisements to be banned:
  - Names, manufacturing methods, efficacy, or performance of drugs, etc. shall not be advertised falsely or exaggeratedly.
  - No news article shall be used for drugs to make people misunderstand that doctors, dentists, herb doctors, veterinarians or other persons guarantee the efficacy or performance of drugs, etc.
  - No efficacy or performance of drugs, etc. shall be advertised by suggestive news articles, photographs, designs and other suggestive methods.
  - No documents or designs which suggest induced termination of pregnancy shall be used with respect to drugs.
- Names, manufacturing methods, efficacy or performance of drugs, etc. shall not be advertised without obtaining a licence or submitting a report, for which a manufacturing or import product registration has been obtained from the health authorities.
- Matters necessary for the scope of advertisement of drugs and other necessary matters shall be prescribed by ordinance of the Prime Minister.
- Drugs can be advertised through media such as print, broadcast and internet, but the relevant advertisement must be reviewed and approved by the MFDS.
- Direct-to-consumer mass advertising of ethical drugs to consumers by means such as print, broadcast and internet is prohibited. However, direct-to-consumer advertisements of certain vaccines for infectious diseases designated by statute are permitted, as well as advertising in professional and academic media that is targeted at medical experts.
- The Korea Fair Trade Commission ('KFTC') can also regulate advertising of drugs that is false, misleading, exaggerated or makes use of unfair comparisons under the Act on Fair Labelling and Advertising ('AFLA').

— **Restrictions concerning medical devices**

- The Medical Devices Act regulates labelling and advertisement of medical devices. Article 24 of the Medical Devices Act prohibits the following:

  (1) Advertisements that contain falsehoods or exaggerations regarding the name of a medical device, its manufacturing methods, performance, efficacy or effectiveness, or principles of operation.

  (2) Advertisements that are likely to mislead people into believing that doctors, dentists, traditional medicine specialists, veterinarians or other persons guarantee, recommend, certify, instruct use of or recognise the performance, efficacy or effectiveness of the medical device, or that such persons have used such device.

  (3) Advertisements that use suggestive articles, photographs, drawings or other materials regarding the performance, efficacy or effectiveness of a medical device.

  (4) Advertisements that encourage abortion or make use of obscene text or images.

  (5) Advertisements that make use of the name, manufacturing methods, performance, efficacy or effectiveness of a medical device that has not been approved.

  (6) Advertisements in mass media such as daily newspapers, television or radio which have not been subject to prior review and approval, or advertisements whose contents differ from what has been approved.

  (7) Any other advertisements prohibited by the MOHW.

- Mass media advertisements such as daily newspapers, television or radio must obtain prior approval from the MFDS. Advertisements in certain professional media are exempt from this prior approval requirement.
- The KFTC can also regulate advertising of medical devices that is false, misleading, exaggerated or makes use of unfair comparisons under the AFLA.

Packaging and Labelling

Regulation of packaging and labelling of medicinal products.

— **Labelling of Containers**

- On the containers or packages of drugs, the following information should be indicated. However, some of the following information may be omitted or only some of the following information may be indicated, as prescribed by ordinance of the Prime Minister (Pharmaceutical Affairs Act, Article 56):

  (1) Trade name and address of a person who has obtained marketing approval of drugs or an importer (in cases of contract manufacturing business, trade name and address of a factory shall be included);

  (2) Name (as for drugs listed in the Korean Pharmacopoeia, the names provided for in such Pharmacopoeia, and as for other drugs, general names);

  (3) Manufacturing number and expiration date;

  (4) Weight, dosage, or quantity;

  (5) Mandatory information in labels of containers or packages prescribed by the Korean Pharmacopoeia;

  (6) As for drugs, the standards for drugs set by the MFDS, the storing methods and mandatory information in labels of the containers or packages of such drugs in accordance with such standards;

  (7) As for drugs not listed in the Korean Pharmacopoeia, names of active ingredients (if general names exist, such names shall be indicated) and quantity (if active ingredients are not clear, the essence thereof and outline of manufacturing methods shall be indicated);

  (8) Letters of 'prescription drug' or 'over-the-counter drug' [in cases of safe and readily available drugs, letters of 'over-the-counter (safe and readily available) drugs];

  (9) Information provided on package inserts;

  (10) Other information prescribed by ordinance of the Prime Minister.

— **Package Inserts**

- The following information must be indicated in package inserts for drugs (Pharmaceutical Affairs Act, Article 58)

  (1) Directions, doses, and other precautions necessary for use or handling;

  (2) As for drugs listed in the Korean Pharmacopoeia, mandatory information in package inserts for drugs or labels of containers or packages of drugs provided for in the Korean Pharmacopoeia;

  (3) As for drugs, the standards determined under Article 52 (1), mandatory information in package inserts for drugs or labels of containers or packages of drugs in accordance with such standards;

  (4) Other information prescribed by ordinance of the Prime Minister.

— **Legally Prohibited Labelling**

- The following shall not be included or indicated in the documents added to the drugs, or on the label for containers or packages (Pharmaceutical Affairs Act, Article 60):
  - False or misleading statement regarding a drug;
  - Efficacy or effect that is not permitted or reported under the Pharmaceutical Affairs Act; and
  - Direction, dosage or period of use which is dangerous to public health and sanitation.
- The KFTC can also regulate labelling that is false or misleading under the AFLA.

— **Identification of the Manufacturing Location and Principal Place of Business on the Label**

- In the case of imported drugs, the manufacturer's trade name and address must be indicated on the label (Enforcement Regulation on the Safety of Pharmaceuticals, etc., Article 69, Paragraph 1), however, for a pharmaceutical ingredient, it is not required.

Regulation of packaging and labelling of medical devices

— **Labelling on Containers**

- The following descriptions shall be labelled on a container or an outer package of a medical device; provided, that the foregoing shall not apply to certain sized containers or outer packages or medical devices as prescribed by ordinance of the Prime Minister:

(1) The trade name and address of the manufacturer or importer;

(2) If imported, the manufacturing origin (the name of the country and the manufacturer);

(3) Licence (certification or report) number and the name of the product, item or model, if a name is available;

(4) The manufacturing number and the date of manufacture (the use-by date may be stated in lieu of the date of manufacture, if a use-by date exists);

(5) Weight or packaging unit;

(6) A label stating 'medical device';

(7) A 'single-use only' and 'do not reuse' label for a single-use medical device.

— **Labelling on Package Inserts**

- A package insert of a medical device shall include the following:

(1) The method of, and precautions for, use;

(2) Instructions for maintenance and inspections, if maintenance and inspections are required;

(3) Matters that the MFDS requires to be described pursuant to Article 19;

(4) Other matters prescribed by ordinance of the Prime Minister.

- The above shall be written at a position more noticeable than any other letter, article, picture, or symbol and shall be written accurately in Korean language with easily comprehensible terms, as prescribed by ordinance of the Prime Minister.

— **Legally Prohibited Labelling**

- The following shall not be included or indicated on a container, outer package, packing material, or package insert of a medical device (Medical Devices Act, Article 24):

(1) A false or misleading description;

(2) Any performance, efficacy, or effect not included in the approval or certification granted or the notification filed with the MFDS;

(3) A method or period of use that is likely to cause harm to the public health or hygiene.

- The KFTC can also regulate labelling that is false or misleading under the AFLA.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system, and how is it funded?

— **Structure**

- The National Health Insurance Program covers the entire population residing in Korea and provides the insured with equal insurance benefits.
- The Medical Aid Program is a public assistance scheme to secure and assist with lives of low-income households.
- The Long-Term Care Insurance Program meets the needs of senior citizens who have difficulties in their everyday lives.

— **Funding**

- Major sources are contributions collected from the insured based on their economic power and government subsidies.

How are prices of medicinal products regulated?

- With respect to treatment materials of which prices can be determined separately from medical treatments and prescription drugs subject to reimbursement by the National Health Insurance Program, the MOHW publishes a list of approved products and maximum prices in the form of a ministry notification.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

- For prescription drugs listed in the notification by the MOHW, patients generally pay only 30% upfront and 70% is funded directly by the NHIS.
- For treatment materials listed in the notification by the MOHW, patients make a copayment as determined in the notification upfront and the remaining amount is funded directly by the NHIS.

Clinical Trials

— **For Pharmaceuticals**

- A person who intends to conduct a clinical trial or a biological equivalence test using drugs must prepare a protocol thereof and obtain approval of the protocol from the MFDS under the Pharmaceutical Affairs Act.
- However, approval of a protocol from the MFDS is not required if such trial or test is aimed at examining clinical effects of a drug already in distribution or investigating whether an adverse event occurs, provided that such drug is already approved or notified.
- All clinical trials for pharmaceuticals must be conducted in accordance with the Good Clinical Practices as set out in the Regulations on Approval of Clinical Trials for Pharmaceuticals.

— **For Medical Devices**

- A person who intends to conduct a clinical test using a medical device must prepare a clinical test plan and obtain approval thereof from the MFDS pursuant to the Medical Devices Act.
- A person who intends to manufacture or import a medical device for approved clinical tests is required to manufacture it in a manufacturing facility that meets the Korea Good Manufacturing Practice ('**KGMP**') or import one manufactured in a facility that satisfies KGMP.
- All clinical trials for medical devices must be conducted in accordance with the Good Clinical Practices as set out in the Regulations on Approval of Clinical Trials for Medical Devices.

Restrictions on dealings with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

- Giving and receiving improper economic benefits for the purpose of increasing sales of products is strictly prohibited under the Pharmaceutical Affairs Act and Medical Devices Act.
- SGA, a general anti-corruption law came into force as of 28 September 2016. This new act applies to all healthcare professionals ('**HCPs**') of national and public university hospitals, HCPs who hold faculty positions at private university hospitals, and all other HCPs who may fall under the scope of public officials.
- The Korean version of the 'Sunshine Act' has recently come into force on 3 June 2017. The Medical Devices Act requires all pharmaceutical and medical device companies to establish and maintain an expense reporting system to collect, keep records of, and report (if requested by the MOHW) on economic benefits provided to HCPs.

Reform

Are there proposals for reform and when are they likely to come into force?

- The government recently introduced a new plan to significantly reform the National Health Insurance Program that will greatly reduce the medical expenses of patients, especially those in the low-income bracket, while providing new and enhanced benefits.
- The plan, which is expected to involve a number of legislative reforms, will begin immediately and continue through 2022.

Singapore

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**

- The Sale Of Drugs Act
- The Medicines Act
- The Health Products Act ('HPA')

— **Main Regulatory Authorities**

- The Ministry Of Health
- The Health Sciences Authority ('HSA')

How are pharmaceuticals (human and animal) and medical devices registered for import?

— **For Registration of Imported Pharmaceuticals**

- A company requires a Product Licence which must be obtained from the HSA before importing medicinal products. If a company does not have a Product Licence, it must then obtain an Import Licence under the Medicines Act. The Import Licence will only be issued to a local importer who has been authorised by the Product Licence holder to import the licenced product. A company must also demonstrate its compliance with HSA's Good Distribution Practice Standard before the granting of the Import Licence will be considered.

— **For Registration of Imported Medical Devices**

- Applicants should register the device with the HSA, and also obtain a Dealer's Import Licence under the Health Products Act. Both of these can be done concurrently.

— **Product Registration**

  – Product registration is mandatory unless a product:

  - Is not a medical device;
  - Is being imported only for re-export purposes; or
  - Is exempt under the Health Products Act as a Class A Medical Device in a non-sterile state.

  – Medical product registration will take one of three routes: abridged, full evaluation or expedited evaluation route.

— **Dealer's Import Licence**

  – To obtain a Dealer's Import Licence, a company must submit evidence of either a Good Distribution Practice for Medical Devices in Singapore (GDPMDS) certification ISO 13485 certification, a Quality Management System for Class A Medical Devices application or a declaration of exemption from GDPMDS. The importer must also provide either a list of exempted Class A medical devices imported or a declaration letter of non-dealing in exempted Class A medical devices.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

— **For Pharmaceutical Registration**

- To manufacture a medicinal product, a company needs to obtain a Manufacturer's Licence under the Medicines Act.
- The company's manufacturing facilities will need to be inspected and be certified as in compliance with the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for Medicinal Products before a Manufacturer's Licence can be issued.

— **For Medical Device Registration**

- Similarly, a company needs to obtain a Manufacturer's Licence under the Health Products Act. To obtain a Manufacturer's Licence, the company needs to obtain ISO 13485 certification for finished medical products manufacturing before making an online application for the licence.

How are pharmaceuticals (human and animal) and medical devices registered for marketing?

— **For Pharmaceutical Registration**

- A product licence or an import licence is first required before marketing can commence.
- Following marketing approval, certain post-approval obligations must be satisfied (listed in the First Schedule of the Medicines (Licensing, Standard Provisions and Fees) Regulations.

— **For Medical Device Registration**

- Medical devices are regulated for marketing under the HPA and are subject to product registration.
- Importers, wholesalers and manufacturers are required to be licenced under the HPA.

What are the restrictions on advertising medicinal products?

— Before any medicinal product can be advertised in Singapore, the company proposing to advertise the product has to obtain an advertising permit.

— It is prohibited to issue false or misleading advertisements relating to medical products. There is also a prohibition on advertisements claiming to cure, prevent or alleviate some diseases, including but not limited to blindness, cancer, hypertension and diabetes.

— Internet advertising of medicinal products is subject to the same rules as advertising in other mediums.

The regulation of the packaging and labelling of medicinal products

— Medicinal products that are dispensed by healthcare professionals (doctors, dentists, pharmacists) must have the following details on their containers:

  - Name of the person to whom the product is to be administered;
  - Name and address of the medical or dental practice, registered pharmacy, hospital or any other institution where the medicinal product is supplied or dispensed;
  - Date on which the medicinal product is dispensed;
  - Directions for use of the medicinal product;
  - Name of the medicinal product, being either the appropriate non-proprietary name or the proprietary designation;
  - Where the appropriate non-proprietary name is labelled, the appropriate quantitative particulars of the active ingredients of the medicinal product;
  - Expiry date of the product.

— Medical products labelling also needs to comply with the following requirements:

  - The information above should be printed legibly and in a prominent position on the label;
  - If the container is made from a continuous sheet of material, the information above has to be displayed at frequent intervals.
  - All labelling of medicinal products must also be indelible.

What is the structure of the national healthcare system, and how is it funded?

Structure of the National Healthcare System

— Primary Healthcare System, including polyclinics and private medical clinics; hospitals and dental clinics.

— Intermediate and long term care.

— Support Services, including forensic pathology, pharmaceutical services and blood transfusion services.

How is it funded?

— Mixed financing system

  - Government and individuals share the burden of financing the national healthcare system.

How are the prices of medicinal products regulated?

— **Private Sector**

- Prices of medicinal products in the private healthcare sector and generally unregulated, and are left to market forces.

— **Public Sector**

- Standard drugs: subsidised by the Government.
- Non-standard drugs: generally unsubsidised and unregulated.
- Public healthcare institutions are obliged to use generic drugs where available.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— The Government healthcare funding system subsidises medical treatment, medication and hospital bills depending on the social-economic situation of an individual.

— The Ministry of Health maintains a Standard Drug List which lists drugs that have been determined to be essential to the provision of basic health care, and the prices of these drugs are therefore kept at an affordable level.

The clinical trial procedures

— Only the holder of a Clinical Trial Certificate issued by the HSA may conduct the trial.

— All test materials used during the trial must meet the labelling requirements in the Clinical Trial Regulations.

— Clinical records of each test subject have to be kept and made available to the HSA for inspection.

— After the completion of a clinical trial, a report has to be submitted to the HSA within three months (or such longer period as the HSA may allow) detailing the findings.

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— It is an offence under the Medicines Act and the Medicines (Medical Advertisements) Regulations to include the offer of any incentive to promote the sale of a medicinal product;

— It is an offence under the Medicines Act to advertise with purpose of inducing practitioners to prescribe or supply medicinal products;

— It is an offence under the Prevention of Corruption Act for a person to give or receive any gratification as an inducement to or reward for doing or not doing anything in respect of any matter or transaction, actual or proposed. This applies to acts of Singapore citizens outside Singapore.

Are there proposals for reform and when are they likely to come into force?

— None at the moment.

Taiwan

Regulatory Overview

What is the main legislation covering pharmaceuticals in Taiwan and which authorities regulate the sector?

Main Legislation

— Pharmaceutical Affairs Act

- Pharmaceutical Affairs Act Enforcement Rules
- Regulations for Registration of Medicinal Products
- Pharmaceutical Good Manufacturing Practice Regulations
- Standards for Medicament Factory Establishments
- Western Pharmaceuticals Good Distribution Practice Regulations
- Regulations for Governing the Management of Medical Device
- Regulation for Registration of Medical Devices

— Veterinary Drugs Control Act

- Enforcement Rules of Veterinary Drugs Control Act

Main Regulatory Authorities

— The Food and Drug Administration, the Ministry of Health and Welfare (FDA) regulates pharmaceuticals and medical devices.

— The Bureau of Animal and Plant Health Inspection and Quarantine, the Council of Agriculture (BAPHIQ) regulates veterinary drugs.

How are pharmaceuticals (human and animal) and medical devices registered for importation?

Pharmaceuticals

— Companies who obtain a drug dealer licence can import pharmaceuticals. Pharmaceutical firms shall file a registration for the market approval of every drug. The market approval is valid for 5 years and after this period expires a dealer will need to request an extension to be able to continue importing the drug. Pharmaceutical firms can be authorised by the market approval holder to import specific pharmaceuticals, but the simultaneously importation of veterinary drugs is prohibited.

— Pharmaceutical firms who engage in the importation of western pharmaceuticals shall obtain a western pharmaceuticals distribution licence for the administration and distribution of drugs, in accordance with the Western Pharmaceuticals Good Distribution Practice Regulations.

Medical Devices

— Companies who obtain a medical device dealer licence can import medical devices. Pharmaceutical firms shall file a registration for the market approval of every medical device. The market approval is valid for 5 years and after this period dealers will need to request an extension if they wish to carry on importing the device.

— Pharmaceutical firms can be authorised by a market approval holder to import a specific medical device.

Veterinary Drugs

— Companies that engage in importing veterinary drugs are deemed veterinary drug dealers. They shall file a registration for the market approval of every veterinary drug. The market approval is valid for 5 years and if the veterinary drug dealer wishes to import drugs after this period they will be required to request an extension.

— In addition, only companies that have made an application to the local municipal competent authority (for veterinary drug dealer licences), and who have been qualified by them following a compliance inspection, can conduct business.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

Pharmaceuticals

— Companies who obtain a drug manufacturer licence can manufacture pharmaceuticals. Pharmaceutical firms shall file a registration for the market approval of every drug. The market approval is valid for 5 years and to be able to manufacture after this period an extension will be required.

— Pharmaceutical manufacturing shall be undertaken in medicament (pharmaceutical) factories. These factories must be established in accordance with the relevant standards, and have completed factory registrations. Only pharmaceutical firms who have been granted a medicament manufacturing licence from the FDA, after a compliance inspection, can manufacture pharmaceuticals. In addition, a resident pharmacist is required in each medicament factory to supervise the manufacturing.

Medical Devices

— Companies who obtain a medical device manufacturer licence can manufacture medical devices. Pharmaceutical firms shall file a registration for the market approval of every medical device. The market approval is valid for 5 years, and after this term expires the medical device manufacturer will need to request an extension if they wish to carry on importing the device.

— Medical devices manufacturing shall be carried out in medicament factories that are established in accordance with the relevant standards, and who have complete factory registrations. Only pharmaceutical firms that have been granted medicament manufacturing licences from the FDA, following a compliance inspection, can manufacture medical devices.

Veterinary Drugs

— Companies engaged in manufacturing veterinary drugs are deemed veterinary drug manufacturers. They shall file a registration for the market approval for every veterinary drug. The market approval is valid for 5 years and if the veterinary drug manufacturer wishes to continue importing the drug after this period they will be required to request an extension.

— Veterinary drugs manufacturing shall be executed in factories exclusively reserved for manufacturing animal products. The factories must also be established in accordance with the relevant standards, and have completed factory registrations.

How are pharmaceuticals (human and animals) and medical devices registered for marketing?

Pharmaceuticals

— Companies engaged in the wholesale and retail of pharmaceuticals shall acquire a drug dealer licence. Selling veterinary drugs at the same time is prohibited. The wholesale of pharmaceuticals requires a western pharmaceuticals distribution licence.

— Companies who obtain drug manufacturer licences can concurrently engage in retailing their own products.

— Pharmacies who obtain pharmacy licences can concurrently engage in retailing pharmaceuticals without applying for a drug dealer licence.

Medical Devices

— Companies engaged in the wholesale and retail of medical devices shall acquire a medical device dealer licence.

— Pharmacies who obtain a pharmacy licence can concurrently engage in retailing medical devices without applying for a medical device dealer licence. The scope of medical devices that can be simultaneously sold by pharmacies includes class 1 medical devices, and non-implantable class 2 and class 3 medical devices; these are specified in accordance with the Regulations for Governing the Management of Medical Device.

Veterinary Drugs

— Companies engaged in the wholesale and retail of veterinary drugs are deemed as veterinary drug dealers. Only companies who have made applications to the local municipal competent authority for a veterinary drug dealer licence, and then who have been qualified by the authority following a compliance inspection, can conduct business.

Advertising

What are the restrictions on advertising medical products?

— Interviews, news reports, or propaganda containing information implying or suggesting medical efficacy will be deemed as medicament advertisements; only pharmaceutical firms can make medicament advertisements. Pharmaceutical firms shall acquire approvals for publishing or broadcasting medicament advertisements. The approval is valid for 1 year and after this an extension is required to carry on advertising.

— Medicament advertisements are prohibited from being publicised by any improper means, including, but not limited to, making use of the name of another person, or warranting the efficacy or functions of the medicament by making use of books or publication materials, or publicising by means of interviews or news reports.

Packaging and Labelling

Regulation of the Packaging and Labelling of Medical Products

— The labels, package inserts and packaging of medical products shall include specific information, including but not limited to, the name and address of the manufacturer; the name of the medicament and the permit licence number; the lot number; the date of manufacture and the period of validity or shelf-life; the major ingredients; the dosage and the method of administration; and the major medical efficacy, functions, indications, reactions, counter-indications and other warnings.

— Pharmaceutical firms that are engaged in manufacturing and importing pharmaceuticals shall indicate in Chinese the label, package insert, and/or packaging to be able to sell, or conduct the wholesale or retail of pharmaceuticals.

— The packaging of pharmaceuticals, including any repackaging, shall conform to the good manufacturing practices for western medicinal products under the Pharmaceutical Good Manufacturing Practice Regulations.

Pricing, State Funding and Reimbursement

What is the structure of the national healthcare system, and how is it funded?

The main national healthcare system in Taiwan is National Health Insurance (NHI), which has been implemented since 1995; NHI covers 99.6% of Taiwan's residents according to statistics released in 2018. NHI allows insured residents to receive medical services at contracted medical care institutions. In addition, according to statistics released in 2017, the percentage of contracted medical care institutions is already over 90%.

The scope of medical coverage includes outpatient and inpatient care, maternity care, physiotherapy and rehabilitation, home health care, and chronic mental illness rehabilitation. The insured are categorized into six classes, and the insurance premium borne differs from class to class. Class 1, which covers civil servants and employees of publicly or privately owned institutions, is the most general; the insured bear 30% of the insurance premium.

How are the prices of medical products regulated?

The price of NHI pharmaceuticals is set and adjusted by the FDA, in accordance with its operating procedures for the adjustment of pharmaceuticals of NHI. Pharmaceutical firms and contracted medical care institutions are obligated to declare the activity price of the pharmaceuticals to the FDA.

Clinical Trials

Any medical institution or pharmaceutical firm that would like to conduct a clinical trial needs to upload a summary of the protocol (including the name of the sponsor, the name of the pharmaceutical, the number of the protocol, the title of the protocol, the purpose, the indication, the institution, the phase, the likely duration of the protocol, the name and phone number of a contact person, the main inclusion/exclusion conditions and the number of subjects) to the website of the Center for Drug Evaluation. They must also submit a hard copy of the protocol to Center for Drug Evaluation in the 7 days before they make an application to the FDA, in accordance with the Application Guide to Pharmaceutical Clinical Trial. The medical institution or pharmaceutical firm shall submit the protocol to the Institutional Review Board of the qualified hospital as well. Only after the protocol is approved by both the aforementioned organisations can the clinical trial go ahead.

In order to simplify the process, any medical institution or pharmaceutical firm that would like to file a protocol of an investigational new drug (IND) that has an identical protocol number approved by the U.S. Food and Drug Administration, only needs to submit the following certificate documents to the FDA for examination: (a) Affidavit letter, (b) Letter of approval of the protocol number issued by the U.S. Food and Drug Administration, (c) Sponsor submit protocol letter and Form FDA l571, (d) FDA IND Acknowledgement letter, and (e) Consent letter of the Institutional Review Board of the qualified hospital in the United States.

Restrictions on Dealings with Healthcare Professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Medical practitioners or institutions who: attend medical conferences held by pharmaceutical firms, receive gifts, conduct research into pharmaceutical firms, or who serve as consultants in the pharmaceutical firm, shall be regulated by the code of the Relationship between Medical Practitioners and Pharmaceutical Firms. Medical practitioners who violate the code may be deemed as violating medical ethics in professional practice under the Physicians Act.

Reform

Are there proposals for reform and when are they likely to come into force?

"Patent Linkage" has been updated at the end of 2017 while the relevant clauses have not come into force. A market approval holder of the new drug could submit patent information of the new drug to FDA, and if there is any pharmaceutical firm would like to file a registration for the market approval for its generic drug, the examination process of market approval for the generic drug would be suspended before the patent infringement dispute has been resolved.

Thailand

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**

- The Drug Act 1967, as amended ('Drug Act').

— **Main Regulatory authorities**

- The Food and Drug Administration ('FDA') of Ministry of Public Health ('MOPH').
- The Drug Control Division of the MOPH.

How are pharmaceuticals (human and animal) and medical devices registered for import?

For Pharmaceuticals

An import licence is necessary for the distribution of modern and traditional drugs in Thailand. The Thai FDA and the Provincial Public Health Offices are the responsible authorities for the importation of drugs. In order to obtain a licence you must:

— Be the owner of the business and have sufficient assets and structure to be able to establish and operate the business;

— Be at least 20 years old;

— Have not been convicted for an offence against certain laws, such as laws concerning narcotics and psychotropic substances;

— Have the premises to sell, import, or store drugs and equipment for use in the production, sale, or storage of drugs, and the control of maintenance of drug quality and quantity as prescribed in ministerial regulations; and

— Use a trade name for the drug business that is not a repetition of, or similar to, the trade name used by another active licencee or a licencee whose licence has been suspended or revoked for less than a full year.

After obtaining the import licence, traders must then register the product with the Thai Food and Drug Administration.

For Medical Devices

— The Medical Device Control Division ('MDCD') of the Thai Food and Drug Administration regulates and monitors the import of medical devices in Thailand.

— First, it is essential to note that only locally-established companies can import medical devices in Thailand.

— The requirements vary depending on whether the device falls under Class I – Licenced Medical Devices, Class II – Notification Medical Devices, or Class III – General Medical Devices.

  • Class I is the most strictly controlled class and concerns for example devices that support human life or prevent a potential or unreasonable risk of illness or injury.

  • Regarding Class II, it is only required to notify the FDA of the devices.

  • Finally, the requirements for Class III products are the least stringent.

How are pharmaceuticals (human and animal) and medical devices registered for manufacturing?

Separate regimes exist for the registration of pharmaceuticals and medical devices.

— **For Pharmaceuticals Registration**

  – Licences are required for the manufacture of pharmaceuticals. Separate licensing regimes exist for 'modern medicines', 'traditional medicines' and 'generics'.

  – **Modern and Traditional Medicines Registration**

  • Applications made in Bangkok are made to the Drug Control Division of the FDA.

  • Applications in provinces other than Bangkok are made to the appropriate provincial public health office.

  • After submitting an application to manufacture a modern medicine, the applicant's premises will be examined by the MOPH to assess compliance with the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Manufacturing Practices (GMP).

  • The MOPH also assesses the adequacy of facilities and personnel to manufacture the proposed medicines.

— **Generic Drug Registration**

  • Generics enjoy an abridged registration process.

— **For Medical Devices Registration**

  – All companies manufacturing medical devices are required to have a Place of Business Registration (an establishment licence).

  – Additional registration requirements vary depending on the type of device being manufactured:

  • Class (1) medical devices require a licence.

  • Class (2) medical devices do not require a licence. However, notification of manufacture of a class (2) medical device must be submitted to the FDA.

  • All medical devices which are not classified as class (1) or class (2) fall within the class of 'general medical devices'. The applicants also need to submit documentation to the FDA.

How are pharmaceuticals (human and animal) registered for marketing?

— Applications to market pharmaceuticals or medical devices are made to the FDA.

— Registration of a new modern drug requires an application to the Drug Control Division of the FDA for permission to import a drug sample into Thailand or, less frequently, permission to manufacture a sample. The sample and application must be submitted to the FDA.

— Marketing approval of pharmaceuticals is indefinite. However, if a product is not on the market for two continuous years, the FDA will automatically cancel the registration.

What are the restrictions on advertising medicinal products?

Restrictions

— Advertising must be pre-approved by the FDA. An advertisement shall not:

  - Boast that a medicine can miraculously or absolutely treat, cure or prevent disease or illness.
  - Exaggerate or falsely declare properties of the medicine.
  - Give the impression that the drug has a substance as its chief or component ingredient that it either does not have, or has in a lower quantity than believed to be present.
  - Give the impression that it is an aphrodisiac or a birth control drug.
  - Advertise specially controlled drugs or dangerous drugs.
  - Cause consumers to misunderstand that the drug is equivalent to other products, such as food or cosmetics.
  - Encourage acts or activities contrary to law.

— Advertisements for prescription or pharmacy dispensed medicines can only be targeted to professionals.

— Drugs in the household remedy category, and drugs not considered to be dangerous drugs, can be advertised directly to consumers and the general public. It is prohibited to advertise medicinal products on the internet, by email or by mail order.

The regulation of the packaging and labelling of medicinal products.

— All labels must be FDA-approved. Package inserts, a Summary of Product's Characteristics and a Patient Information Leaflet must be submitted to the FDA for approval.

— Package inserts must contain the following:

  - Product name;
  - Name and strength of the active ingredients;
  - Product description;
  - Pharmacodynamics/pharmacokinetics;
  - Indications;
  - Recommended dose;
  - Instructions for use;
  - Dosage forms and packaging available;
  - Name and address of manufacturing/marketing authorisation holder;
  - Date of revision of package insert.

— A package label must include the following mandatory information:

  - Product name;
  - Registration certificate number;
  - Content, composition or active ingredient with the quantity/potency;
  - Lot/batch number & manufacturer's name and country of origin;
  - Date of manufacture, expiration date and the word 'expiry' in Thai.
  - If applicable, and on a red label, a statement that the drug is classified as a specially controlled drug, dangerous drug, or common household drug in Thailand.

— All of the above information can be in Thai or English, except for the information noted above that must be expressly stated in Thai.

— Other information may be required to be incorporated into labels as required by the FDA from time to time.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system and how is it funded?

— Thailand has universal healthcare coverage. The national healthcare system is divided into three main schemes:

- **The Social Security Scheme:** private employees. (However, some categories of employees are exempt from this scheme).
- **The Civil Servant Medical Benefit Scheme (CSMBS):** civil servants and their families (parents and up to three children).
- **The National Health Insurance (THB30) Scheme:** the remaining population not covered under either the Social Security Scheme or the CSMBS.

How are the prices of medicinal products regulated?

— Drugs that can be used by Government hospitals are listed on the National List of Essential Drugs (NLED).

— The prices of the drugs on this list are subject to a median price policy.

— Additionally, prices are prescribed for drugs to be administered to persons under the CSMBS.

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— Reimbursement is available for drugs listed on the NLED.

— Drugs may be provided free of charge, or, for people under the THB30 Scheme, a maximum of THB30 is charged in certain circumstances.

— The hospital is reimbursed completely by the Government.

— Medical devices are not listed on the NLED.

— However, reimbursement of some medical therapy equipment and artificial organs for persons under the CSMBS is permitted.

— Reimbursement is partially covered for persons under the Social Security Scheme if the medicinal product was administered by a doctor in a Government hospital.

The clinical trial procedures

— To date there is no centralised regulation for clinical trials.

— Trial pre-conditions and recruitment of the participants should be outlined in the initial submission to the Ethical Review Committee for Research in Human Subjects (ERC) of the MOPH.

— A sponsor must first obtain approval to conduct a study on humans from the ERC and/or the ethics committee of the research institute or university that will conduct the trial.

— The drug sponsor can then apply to the FDA for a licence to import investigational drugs into Thailand for research purposes.

Restrictions on dealings with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— There are no general restrictions on marketing practices.

— However, some restrictions apply to the conduct of individuals.

— State officials can only receive property or any other benefit from any person (other than a relative) if the value of the benefit received from each person, and on each occasion, does not exceed THB3,000.

— Pharmacists or officers who are not employed by the Government are restricted by the PReMA Code, which provides detailed restrictions on marketing.

— Traditional or customary courtesy gifts to healthcare professionals or institutions are allowed. However, such a gift must be infrequent and must not exceed THB3,000.

— The Pharmaceutical Reseach & Manufacturers Association (PReMA) Code precludes gifs to hospitals and medical institutions.

Reform

Are there proposals for reform and when are they likely to come into force?

— There are currently three Bills under review that concern the pharmaceutical industry:

- A Drug Bill has been drafted. The Bill covers civil liability, price controls and many other issues.
- The Trade Mark Bill will change the trademark regime.
- The Patent Bill is currently under consideration.

— These Bills are in the early stages of consideration.

— It is unlikely that the Bills will enter into force in the near future.

— The Food and Drug Administration (FDA) Notification re: Documentation for Registration of Biosimilar 2013 provides the lists of documents and evidence that biosimilar registration dossier must be submitted to the Thai FDA.

Vietnam

Regulatory Overview

What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

— **Main Legislation**

For human pharmaceutical products

– The Law on Pharmacy No. 34/2005/QH11 and its implementing legislative documents, including:

- Decree No. 79/2006/ND-CP.
- Decree No. 102/2016/ND-CP.
- Circular No. 44/2014/TT-BYT.

A new Law on Pharmacy No. 105/2016/QH13 was passed on 6 April 2016 will take effect on 1 January 2017. Corresponding implementing documents are expected to be issued later in 2016.

For animal pharmaceutical products

– The Law on Veterinary Medicine No. 79/2015/QH131 and its implementing legislative documents, including:

- Decree No. 35/2016/ND-CP.
- Circular No. 13/2016/TT-BNNPTNT.

For medical devices

- Decree No. 36/2016/ND-CP.

— **Main Regulatory Authorities**

- The Ministry of Health ('MOH').
- The Drug Administration of Vietnam ('DAV').
- The Ministry of Agriculture and Rural Development ('MARD').
- The Department of Animal Health ('DAH').
- The Department of Medical Equipment and Health Works ('DMEHW').

How are pharmaceuticals (human and animal) and medical devices registered for import?

— **For pharmaceutical (human) registration**

- Application for marketing authorisation licence ('MA') must be made in standard form and submitted to the DAV under the MOH.
- The registration dossier must be prepared in ACTD format.
- Normally, the validity of an MA is five years. In some special cases validity may be given for one or two years only.
- Additionally, pharmaceuticals (without an MA) may be imported by a specific import licence ('Import Licence') issued by the MOH. An Import Licence is applied for drugs containing pharmaceutical ingredients with or without registration number, which are: (i) insufficient to meet medical treatment needs; or (ii) need to be imported to meet urgent needs of epidemic prevention and combat and overcome consequences of natural disasters, and special medical treatment needs. The validity of an Import Licence is one year with a defined quantity.

— **For medical device registration**

- Medical devices are classified into two groups, with four types from type A to D based on potential risks related to the design and production of such medical devices. Group 1 includes type A medical devices with low potential risk. Group 2 includes type B, C and D medical devices with lower average, upper average and high level of risks, respectively.
- Type A medical devices must be declared with the provincial Department of Health ('DOH') regarding their applied technical standards and must obtain a Circulation Number ('CN') before being imported and circulated in Vietnam.
- Type B to D medical devices are required to be registered with and obtain a CN from the DMEHW before being imported and circulated in Vietnam.
- The CN of type A medical devices will be permanently effective while the CN for type B to D medical devices will be effective for five years from the date of issue.

— **For veterinary drug (animal) registration**

- Application for an MA must be submitted to the DAH under the MARD.
- The validity of an MA is five years from the granting date.

How are pharmaceuticals (human) and medical devices registered for manufacturing?

— **For Pharmaceutical Registration**

Companies can manufacture pharmaceutical products in Vietnam if they satisfy the below conditions:

- Have incorporation certificates required by the Enterprise Law and Investment Law with appropriate registered business line of 'drug manufacturing'.
- Have Certificate of Business Eligibility ('CBE') in drug manufacturing.
- Have Certificate of Good Manufacturing Practice, equal to WHO-GMP or higher ('GMP').

To obtain the CBE and GMP, companies must satisfy certain conditions about human resources, construction, equipment, etc., and must submit a registration to the MOH for validation. The CBE and GMP will be permanently effective.

— **For Medical Device Registration**

Companies can manufacture medical devices in Vietnam if they satisfy the below conditions:

- Have incorporation certificates required by the Enterprise Law and Investment Law with appropriate registered business line of 'medical device manufacturing'.
- Have CBE in medical device manufacturing.

To obtain the CBE, companies must satisfy certain conditions about human resources, construction, equipment, etc., and must submit a declaration dossier to the provincial DOH for validation.

How are pharmaceuticals (human) registered for marketing?

All pharmaceutical products must be registered with and obtain approval from competent authorities for marketing activities. There are certain types of marketing activities allowed for drugs including:

- Sales promotions activities such as giving discounts, lucky draws, loyalty programs, etc.
- Drug introduction via seminar and drug introducers (medical representatives).
- Provision of drug information material to healthcare professionals.
- Advertising

Companies must notify the provincial Department of Industry and Trade for sales promotions activities. For drug advertising, it is required to submit registration dossiers to the DAV to obtain prior approval. For other marketing activities, companies must submit registration dossiers to the DOH.

Advertising

What are the restrictions on advertising medicinal products?

— It is prohibited to advertise:

- Prescription drugs, vaccines and medical biologicals for disease prevention.
- Drugs that are subject to use under the supervision of a physician or without valid registration numbers.

— The advertisement of prescription drugs to the general public in any form is strictly prohibited.

— Drug information documents can only be distributed to medical professionals, not to the general public.

— Advertising drugs before obtaining the approvals from the DAV is also prohibited.

— Applicants must obtain approval from the DAV for various aspects of the advertisement, such as content, layout, and form.

— The following acts are also prohibited in relation to advertising:

- Use of names, symbols, images, positions, reputation and mail addresses of medical and pharmaceutical organisations or medical workers.
- Use of patient thank you letters to advertise or recommend drugs.
- Use of drug circulation registration numbers granted by the DAV or foreign drug management agencies to advertise drugs.
- Advertising drugs in the form of physicians' instruction on disease prevention and treatment in newspaper articles and radio or television broadcast programmes, etc.

— In addition, an organisation trading in medicines can only advertise medicines on its lawful website and cannot advertise medicines it does not trade in.

— Entities advertising their own products cannot send an e-mail or text message advertisement without prior consent of the recipients.

Packaging and labelling

The regulation of the packaging and labelling of medicinal products

The label of a drug must contain certain mandatory information in Vietnamese. If the original labels of medical products imported into Vietnam do not bear, or fail to adequately bear, mandatory information in Vietnamese, they must have auxiliary labels in Vietnamese attached while the original labels are kept intact.

The label content and use instruction inserts must be truthful, clear and accurate, and must not be misleading about the true nature and effect of the medicine.

— The following content is mandatory for medicine labels:

Label for secondary package:

- Name of the medicine;
- Active ingredients and their strengths or concentrations;
- Package size;
- Indications, administration, and contraindications;
- Dosage form, registration number/import licence;
- Manufacture date, expiry date, lot number and storage conditions of the medicine;
- Name of manufacturer, name of importer, country of origin; and
- Special signs.

Label for primary package:

- Name of the medicine;
- Name of manufacturer;
- Lot number, expiry date.

All drugs must have two package inserts in Vietnamese, one for patients and one for healthcare professionals. The package inserts must content certain mandatory information as follows:

Package insert for patients:

- Drug name
- Warning texts (if necessary): 'Read the instructions carefully before use'; 'Keep away from children', 'Inform the physician or pharmacist of adverse effects encountered during use' and 'prescription drugs'
- List of active ingredients and corresponding concentration/strength; list of excipients
- Dosage form and description thereof
- Packaging size
- Indications
- Directions, dose and administration route of the drug
- Contraindications
- Adverse effects (if any)
- What drugs or foods should be avoided when using this drug
- Specification of the reactions of the drug with other drugs and other reactions
- What to do when forgetting to take the drug
- Storage conditions and temperature
- Signs and symptoms and manifestations of overdoses
- What to do when having an overdose
- Cautions
- Cases that need consultation with a physician or pharmacist and the text 'Ask a physician or pharmacist for more information'
- Expiration date
- Name, address, and symbol (if any) of the manufacturer
- Updating date of the package insert

Package insert for health care professionals:

- Drug name
- List of active ingredients and corresponding concentration/strength; list of excipients
- Dosage form
- Information about pharmacodynamics and pharmacokinetics of modern medicines or curative reagents
- Packaging size
- Indications, contraindications, dose, and directions
- Cautions
- Reactions of the drug with other drugs and other reactions
- Adverse effects
- Overdose and treatment
- Notes and recommendations
- Storage conditions and expiry date
- Manufacturer's name and address
- Updating date of the package insert.

Pricing, state funding and reimbursement

What is the structure of the national healthcare system?

Currently, the national healthcare system is mandatory for all people and composed of five groups:

1. The group whose insurance is paid by employers and employees
    - Employees on indefinite or at least three-month contracts; salaried business managers; officials and civil servants.
    - Part-time officers in communes, wards and towns.

This scheme is partially funded by contributions from those included.

2. The group whose insurance is paid by social insurance organizations
    - Persons receiving monthly retirement pensions and compensation for loss of capacity for work.
    - Persons receiving monthly social insurance pensions due to occupational accidents or diseases or diseases needing long-term treatment; beneficiaries at the age of 80 or above.
    - Officers in communes, wards and towns who have left employment and been receiving monthly social insurance benefits.
    - Persons receiving unemployment benefits.

This scheme is funded by social insurance organizations.

3. The group whose insurance is fully paid by the State budget
    - Officers, soldiers, students who are working and/or studying in military and police sector and their relatives.
    - Persons receiving monthly compensation from State.
    - Persons performing meritorious services in the wars, war veterans and their relatives.
    - Incumbent deputies of the National Assembly or the People's Councils at all levels;
    - Children under the age of 6;
    - Persons receiving monthly social protection pensions;
    - Members of poor households, ethnic minorities living in regions facing socio-economic difficulties, persons living in regions facing extreme socio-economic difficulties; persons living in island communes or districts.
    - Persons who have donated body parts under the regulations of the law;
    - Foreigners studying in Vietnam that are granted scholarships funded by the Vietnam State budget.
4. The group whose insurance is partially paid by the State budget
    - Members of households living above the poverty line;
    - Students.
5. The group of household insured including household members except for the ones prescribed above

How are the prices of medicinal products regulated?

— Medicinal product manufacturers, exporters, importers, marketing authorisation holders, and wholesalers/ distributors are free to set the prices of their products and compete on prices.

— Pharmaceutical establishments must declare their medicinal product prices to the DAV.

— For imported medicinal products, when the applicant has obtained marketing authorisation for the drug, but before the first lot of the drug is circulated in Vietnam, the distributor must declare to the DAV the:

  - Actual CIF price at the Vietnamese port;
  - Estimated wholesale price; and
  - Estimated retail price for the drug.

— The declared drug prices must not be higher than the corresponding prices of drugs of the same types in regional countries with similar medical and commercial conditions to Vietnam. The MOH is responsible for publishing the list of those regional countries, on the basis that those countries have similar economic conditions and healthcare provision.

— The DAV announces on its website the reference price list for medicinal products that have won tenders in hospitals in Vietnam (www.dav.gov.vn).

When is the cost of a medicinal product funded by the state or reimbursed to the patient?

— There is a list of drugs that are paid by the Health Insurance Fund. This list applies to private and Government health establishments that have signed a medical care contract with a health insurance institution.

— These establishments, which are mainly hospitals, have these drugs which won the tender to be supplied directly to patients.

— Winning tender drugs are not distributed through pharmacies.

— Patients must pay for drugs themselves if: (i) they don't have a Health Insurance Card; (ii) the drug is not listed in the list of drugs paid by the Health Insurance Fund; or (iii) the drugs are not listed in the tendering award.

— Pharmacies include hospital pharmacies and private pharmacies which supply drugs to be paid by the patients.

Clinical trials

The clinical trial procedures

— The sponsor prepares and submits an application dossier for registration of a clinical trial to the Science and Training Department.

— The MOH issues an approval letter allowing the sponsor to take the next steps.

— The sponsor and principal researcher submit a product dossier and the protocol for the clinical trial to the Science and Training Department for evaluation.

— The Science and Technology Council evaluates the scientific basis for the trial and the Biomedical Research Ethics Council examines the ethical aspects.

— The Science and Training Department collects the evaluation results and either notifies the sponsors and institution that they need to supplement their application or sends the results to the Minister for approval.

Restrictions on dealings with healthcare professionals

What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

— Using material or financial benefits in any form to induce physicians and drug users to promote the prescription and use of drugs is prohibited. Therefore, giving such sort of gifts of other incentives to healthcare professionals for promotional purposes is illegal. However, in certain occasions such as weddings, Tet (traditional New Year), anniversaries, etc., a small gift may be given.

— The restrictions apply to all Vietnamese healthcare establishments and individuals, regardless of whether the conduct took place in Vietnam or abroad.

— Under the Anti-Corruption Law, state officials are strictly forbidden from taking advantage of the giving or receiving of gifts in order to bribe or perform other acts for self-seeking interests. The threshold for criminal liability is generally VND2 million.

Are there proposals for reform and when are they likely to come into force?

The new Law on Pharmacy No. 105/2016/QH13 dated 6 April 2016 will be effective from 1 January 2017.

Accordingly, the following draft implementing legislative documents are expected to be issued in the end of 2016 so that they will be effective at the same date of the new Law on Pharmacy:

— Draft Circular on drug and raw material labelling.

— Draft Decree on conditions for drug trading.

— Draft Circular guiding on drug registration.

— Draft Decree guiding on drug information and drug advertising.

— Draft Decree on measurements on drug pricing.

IP

Australia

Patents

Describe your jurisdiction's patent system including application procedure, term of patent protection and average time from application to grant

— **Application Procedure**

(i) Filing: The applicant selects the appropriate patent to file from standard, innovation, and international patents. An applicant may choose to file a 'provisional' application, which requires less specification of the claimed invention, in order to secure an advantageous 'priority date'. The application is filed with the Patent Office.

(ii) Publication: The (unexamined) patent is then usually published in the Australian Official Journal of Patents within 18 months.

(iii) Examination: The applicant must request examination within 5 years of the filing date or the application will lapse. After examination, either an adverse report or notice of acceptance is mailed to the applicant. An applicant may change their application to overcome objections in the adverse report.

(iv) Acceptance: Once all objections in the examination report are overcome, the application is accepted and the Commissioner of Patents publishes a notice to that effect.

(v) Opposition: Once the notice of acceptance is published, third parties have three months to oppose registration of the patent (i.e. oppositions are pre-grant). If there are no oppositions within the three month opposition period the application is granted and the patent sealed.

(vi) Fees: Once granted continuation and renewal fees must be paid.

— **Term of protection from application date**

Standard patent: 20 years, with a very limited right to obtain an extension of term for 5 years for patents for pharmaceutical products.

Innovation patents: 8 years.

— **Average time from application to grant**

In 2015 IP Australia reported that the average time from filing to grant of patent was approximately 37 months.

Describe patentable and non-patentable subject matter within the life sciences field

— **Patentable subject matter**

An invention the subject of a standard patent must be a 'manner of manufacture', novel and involve an inventive step when compared with the prior art base, be useful and not have been secretly used before the priority date.

An innovation patent has the same requirements, except that it must involve an 'innovative step' when compared with the prior art base, rather than an 'inventive step'.

By way of example, the Patents Office has found the following subject matter to be patentable.

- Biological processes based on the use of micro-organisms;
- Isolation and cultivation of micro-organisms or a biologically pure culture of a naturally occurring micro-organism;
- New forms of living organism or non-human animal;
- Methods of treatment of the human body; and
- Recombinant of isolated proteins.

— **Non patentable subject matter**

The Commissioner of Patents may refuse to grant a patent where it would be 'contrary to law'.

Human beings and biological processes for the generation of human beings are expressly excluded from patentability in the *Patents Act 1990* (Cth).

Describe patent revocation/invalidation

Any person may apply for an order revoking a patent, and a defendant to a claim for infringement may counter-claim for revocation of the patent. Revocation proceedings are brought before the Federal Court of Australia.

A patent may be revoked on the following bases:

- that the patentee is not entitled to the patent;
- that the invention is not a patentable invention (for any of the criteria of validity);
- that the patent, or an amendment to the patent specification, was obtained by fraud, false suggestion or misrepresentation; or
- that the patent specification does not comply requirements as to form in s 40 of the *Patents Act*.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— **Claim for infringement**

A person infringes a patent if they 'exploit' (defined to include making, hiring , selling, otherwise disposing of, using, importing, keeping for the purpose of doing any of the foregoing, and doing any of the foregoing acts in respect of a product resulting from) the claimed invention, or authorising or inducing another person another person to exploit the claimed invention. A person also infringes a patent where they supply under specific circumstances products whose use would infringe the patent.

Infringement proceedings are brought before the Federal Court of Australia.

— **Available remedies**

The patentee is entitled to declaratory relief (e.g. a declaration that the patent is valid and infringed), an injunction subject to terms that the court thinks fit, and at the patentee's election, either an account of profits or damages. A successful litigant is also entitled to recover its legal costs from the other party (calculated on a prescribed scale). In limited circumstances, the court may award additional damages.

Trade marks

Describe your trade mark system including application procedure, term of trade mark protection and average time from application to grant

— **Application Procedure**

- A person can apply for registration of a trade mark in Australia through the Australian Trade Marks Office. An application is filed online using the Office's eServices facility. The Applicant must specify the mark, nature of mark, Applicant details, goods and/or services to be protected and provide any convention priority details. No formal Power of Attorney or other documents are required in order to file a trade mark application in Australia.
- The usual time frame from filing to registration in Australia (assuming no objections are raised on examination and no oppositions filed) is 8 - 10 months. The minimum period between filing registration and a certificate being issued is usually 7 months from the filing date. This is to account for applications filed in Australia under the Paris Convention which claim an earlier priority date.
- An application, once advertised as accepted, is advertised for opposition for a period of 2 months during which third parties may oppose registration.
- If no oppositions are filed or any oppositions are successfully contested, the application will proceed to registration subject to payment of registration fees.
- Trade mark protection runs for an initial period of 10 years but may be renewed indefinitely subject to payment of renewal fees.

Are there any particular preclusions on life sciences products branding? Any non-INN similar preclusions?

The Australian Trade Marks Office may raise a 'non-distinctiveness' ground for rejection where such a mark is identical or confusingly similar to a notified INN or INN stem. This ground for rejection is also a ground of opposition. Such marks are not considered to be capable of distinguishing the Applicant's goods from those of other traders.

The Australian Trade Marks Office may raise a 'likelihood of deception or confusion' ground for rejection where a mark (or part thereof) to be used in relation to pharmaceuticals or veterinary substances is the same as, or may connote, a notified INN and where use of the trade mark in respect of the goods specified in the application go beyond the substance indicated by the INN. Use of such a trade mark would be likely to give rise to deception or confusion. This ground for rejection is also a ground of opposition.

How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

- There are two typical infringement scenarios. A person infringes a trade mark registration if the person uses as a trade mark (a) a sign that is deceptively similar to a registered trade mark in relation to the registered goods or services, (b) a sign that is deceptively similar to a registered trade mark in relation to similar goods or services. In the case of (b), a defence exists where it can be shown that the manner of use of the impugned mark is not likely to cause confusion.
- Infringement proceedings are brought before the Federal Court of Australia.
- Relief that a plaintiff can seek in an infringement action includes declaratory relief (i.e. a declaration that the trade mark is infringed), an injunction and, at the election of the plaintiff, damages or an account of profits. The court may grant additional damages based on factors such as the flagrancy of infringement, deterrence and conduct of the infringer after being informed of the infringement.

Data protection

Do data protection laws impact on pharmaceutical regulation in Australia?

- The TG Act provides a period of five years of data exclusivity for the first party to file an application to register a new active ingredient. Information provided to the TGA is protected by this data exclusivity protection only if it is about the 'active component' (defined as the substance primarily responsible for the biological or other effect of the therapeutic goods) and it is not already publicly available.

IP and competition law issues

What is the competition law framework and how does it impact on the lifesciences sector?

Australia's competition laws are set out in the *Competition and Consumer Act 2010* (Cth) (**CC Act**). These laws regulate:

- cartel conduct including price fixing, market division, output restrictions (e.g. when competitors agree to restrict the volume of goods or services to be made available), and bid rigging;
- agreements which contain provisions that have the purpose of or are likely to substantially lessen competition;
- corporations with a substantial market power taking advantage of that market power for an anti competitive purpose;
- exclusive dealing (usually wholesalers imposing restrictions on retailers) that has the purpose of or is likely to substantially lessen competition;
- resale price maintenance, where a wholesaler enforces a minimum sale price that retailers must observe; and
- mergers that will have the effect of substantially lessening competition.

There is a limited exception under the CC Act to some of these prohibitions, where the contravention is brought about by the licensing of intellectual property or the assignment of an intellectual property licence. The exception does not apply to misuse of market power and resale price maintenance.

A recent review commissioned by the Government, the Harper Review into Competition Policy released in 2015, recommended that this exception be abolished. The Government requested further review of the exception in a review of Australia's intellectual property regime being conducted by the Productivity Commission. In a draft report, the Productivity Commission reiterated the Harper Review's conclusion that the exception should be repealed. The Productivity Commission's final report is due in August 2016.

In a recent draft review of Australia's IP regime, the Productivity Commission expressed concern regarding 'pay for delay' agreements, in which an originator pays a generic manufacturer to not enter the market beyond the scope of the patent. While acknowledging there have been no cases of 'pay for delay' in Australia to date, the Productivity Commission noted they occur around the world, and was of the opinion they may constitute anti-competitive contracts entered into for the purpose of substantially lessening competition. The Productivity Commission's final report is due in August 2016.

Bolar exception

The *Patents Act 199*0 (Cth) provides that a pharmaceutical patent is not infringed by a person exploiting the claimed invention solely for the purpose of obtaining registration on the ARTG or similar regulatory approval under a foreign regime. Pharmaceutical patents are patents claiming a pharmaceutical substance or methods, uses or products relating to a pharmaceutical substance.

A similar protection exists for doing an act that would infringe a patent if that act is done solely for purposes connected with obtaining approval required by an Australian or foreign law to exploit the claimed invention.

Experimental use of a patented invention to determine its properties, improve it, or assess the validity of the patent will not be considered to infringe the patent.

Parallel importation

Parallel importers must comply with product safety requirements under Australian law, and are required to provide the statutory guarantees relating to product quality and refunds, not only as a supplier, but also potentially as a deemed manufacturer.

The definition of 'exploit' includes importation. Importing a patented product without authorisation will constitute infringement, as will importing a product made overseas using a process patented in Australia.

Compulsory licence

A person may apply for a compulsory licence to work a patented invention if the 'reasonable requirements of the public with respect to the invention' are not being met. The reasonable requirements of the public will not be met where the patented invention is capable of being worked in Australia on a commercial scale, but is not being so worked, or where a trade or industry in Australia is unfairly prejudiced. The applicant must have attempted to gain authorisation to work the invention on reasonable conditions from the patentee, and a period of three years from grant of the patent must have elapsed.

A compulsory licence may also be applied for where a patentee is contravening prohibitions on restrictive trade practices in the *Competition and Consumer Act 2010* (Cth).

There has been very little application of these compulsory licensing provisions.

China

Patents

Describe your jurisdiction's patent system including application procedure, term of patent protection and average time from application to grant

In China, there are 3 types of patents: invention, utility model and design patents.

— **Application procedure**

- National registration
  - Applicant applies directly to the State Intellectual Property Office (SIPO) for patent registration.
  - Preliminary examination.
  - SIPO may grant the patent (utility model and design patent) or publish the patent application (invention patent).
  - Substantive examination.
  - SIPO may authorise the invention patent.
- International registration
  - Applications may be made under the Patent Cooperation Treaty (PCT) with the International Bureau of Intellectual Property.

— **Term of protection - from application date**

- Invention patent – 20 years
- Utility model patent – 10 years
- Design patent – 10 years

— **Average time from application to grant**

- Invention patent – 2.5-4 years
- Utility model patent – 1 year
- Design patent – 3-5 months

Describe patentable and non-patentable subject matter within the life sciences field

— **Patentable subject matters:**

- New chemical entity (NCE)
- New pharmaceutical preparations
- New preparation methods
- New medical applications
- New extracted natural substances
- New extracted microbes
- Products, production methods of gene engineering
- Medical devices

— **Non-patentable subject matters:**

– Natural substances

- Found in nature and existing in its natural state.

– Medical use of Substances

- Used for the diagnosis or treatment of diseases, however if used for the manufacturing of a medicament it may be patentable.

Describe patent revocation/invalidation

Usually filed by a potential infringer in order to counter litigation concerning infringement. An invalidation request is filed with the Patent Re-examination Board of SIPO. The Courts have no initial jurisdiction over patent invalidity.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Exploiting the patent without permission, i.e. for production or business purposes, to manufacture, use, offer to sell, sell, or import the patented products, use the patented method, or use, offer to sell, sell or import the products that are developed directly through the use of the patented method.

— **Claim for infringement**
  – Apply to the authorities for administrative protection & civil lawsuit against the infringer.

— **Available remedies**
  – Injunctions (preliminary and / or final).
  – Compensation (actual losses & benefits acquired by the infringer & reasonably calculated royalties).

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

— **Application procedure**

There are two ways to register trademarks.

— **National registration**

- The applicant applies for trademark registration directly to the China Trade Mark Office (CTO).

— **International registration (Madrid System)**

- The applicant may apply for trademark registration in the home jurisdiction and seek an extension of protection in China through the Madrid System with the International Bureau of Intellectual Property.

— **Term of protection** - from date of grant and can be renewed indefinitely

- National application – 10 years
- Madrid application – 20 years

— **Average time from application to grant**

- 1-2 years

Are there any particular preclusions on lifescience products branding? Any non-INN similar preclusions?

— The INN drug name cannot be registered as a trademark.
— Generic drugs cannot have brand names and related trademarks.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— The use of an identical or similar trademark for identical or similar goods and services creating a likelihood of confusion.
— A trademark right holder can ask the Administrative for Industry and Commerce (AIC) for protection or sue the infringer.
— Available remedies for trademark infringement are similar to those for patent infringement.

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— Available to drugs containing a 'new chemical entity'.
— Data must be undisclosed and developed by the applicant itself.
— A six year period of protection is available.
— The current law is ambiguous as to exactly how data protection is to be implemented.
— In practice, the CFDA has yet to award data exclusivity to any drug.

IP and competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

– China has a comprehensive system of competition law under its Anti-Monopoly Law (AML), which prohibits 'monopolistic conduct', which is defined as:

  • Monopolistic agreements among business operators;

  • Abuse of dominant market positions;

  • Concentration of business operators that eliminates or restricts competition.

– To date there have been very few examples of Lifesciences companies being investigated under the AML.

– The balance between competition law and the protection of intellectual property has been discussed by the Chinese authorities. The Administrative Rules for the Enforcement of AML against the Abuse of Intellectual Property issued by State Administration for Industry and Commerce ('SAIC') came into effect on 1 August 2015. The SAIC has further issued the Guidelines on Anti-Monopoly Law Enforcement against IPR Abuse (draft open for Comment) and the Bureau of Price Supervision and Anti-Monopoly of the National Development and Reform Commission issued the Anti-mMonopoly Guidelines on the Abuse of Intellectual Property (draft open for Comment) in early 2016.

— **Bolar exception**
  • Does not infringe.

— **Parallel import**
  • Does not infringe.

— **Compulsory licence**
  • Recent legislation allows for this but has never been enacted.

— **No supplementary protection**

— **Monitoring Period Exclusivity**
  – The CFDA may impose a 'monitoring period' to observe the safety and efficacy of 'new' drugs.
  – During the monitoring period, the CFDA will not grant approval to other enterprises to manufacture, distribute, or import the drug into China.
  – Only available to drugs manufactured in China, not imported drugs.
  – Protection lasts from 3-5 years.

India

Patents

Describe your patent system including application procedure, term of patent protection and average time from application to grant

— The Patents Act, 1970 ('Patents Act') regulates the regime for patents in India and provides patent protection to innovative products and processes in the various fields of science and technology, including Lifesciences.

— The basic criteria for an invention to be patentable are the following:

- Novelty;
- Inventive step; and
- Industrial application.

— Applications are made to the appropriate patent office which are published and examined.

— Pre-grant opposition can be filed any time after publication but before grant, and will be taken up only after request for examination is filed. Post-grant oppositions/revocations proceedings can be filed after grant of the patent.

— Divisional applications can be filed at any time before patent grant.

— Modifications/improvements to existing patents may be protected by patents of addition.

— Being a signatory to the Paris Convention, and the Patent Cooperation Treaty, foreign applicants can file patent applications in India claiming priority on basis of patent applications filed in their respective foreign jurisdiction.

Describe patentable and non-patentable subject matter within the Lifesciences field

— **Patentable subject matters**

- Gene sequences that have been modified would be considered patentable.

— **Non-patentable subject matters**

- Biological materials, including gene sequences, solely isolated from nature are considered prima facie non-patentable;
- Methods of treatment;
- Methods of agriculture/horticulture;
- Computer program per se.

— Please note that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers mixture and complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in property with regard to efficacy. Patent applications have been rejected in cases where the new molecule in relation to drugs does not showcase any increase in therapeutic efficacy.

— Attempting to extend the monopoly over known subject matter also known as 'before Ever-greening' of patents by claiming any of the new forms listed above is not permissible unless 'enhanced efficacy' of the new form is shown.

— An Indian patent accords protection to an invention across India for a maximum term of 20 years, if renewal fees are paid annually.

— The 20 year term is calculated from the filing date of the application in India.

— Average time from filing application to grant is between 2 (two) to 3 (three) years.

Describe patent revocation/invalidation

— A patent application can be opposed before grant, and a patent can be opposed within a year of publication of grant or revoked any time thereafter on various grounds provided in the Patents Act.

— A patent may be revoked in the following circumstances:

- On petition of any person interested, by the Intellectual Property Appellant Board ('**IPAB**');
- On petition of the Central Government, by the IPAB;
- On a counter claim by a defendant of a patent infringement suit, by the High Court;
- By the Central Government, under certain circumstances (e.g. if a patent is prejudicial to the public); and
- By the Controller, on application by a person interested or the Central Government, due to non-working of the patent for 2 (two) years after the grant of a compulsory licence in respect of that patent.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— A suit for infringement of patent may be instituted by the plaintiff in a 'District Court' having jurisdiction to try the suit. However, where a counter- claim for revocation of the patent is made by the defendant, the suit, along with the counter- claim, is transferred to 'High Court' for decision.

— An act of infringement is not defined in the Patents Act and so any violation of the rights of patentees may be construed as an act of infringement.

— The burden of proof is usually on the claimant but may be shifted to the defendant if the patentee is unable to determine the process actually used by the alleged infringer. The Patents Act provides the following reliefs which may be granted by a Court of law for suits regarding infringement of patents:

- Injunctions;
- Damages;
- Account of profits; and
- The Court may also order that infringing goods shall be seized, forfeited or destroyed, as the Court deems fit under the circumstances of the case without payment of any compensation.

Compulsory licensing regime in India

— Under the Patents Act, any time after the expiration of 3 (three) years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence.

— The compulsory licence on a patent is granted if:

  - The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
  - The patented invention is not available to the public at a reasonable affordable price; or
  - The patented invention is not worked in India.

— The Controller, while granting the compulsory licence is required to take into account factors such as the nature of the invention, measures already taken by the patentees to make full use of the invention, ability of the applicant to work the invention to the public advantage, time elapsed since the grant of the patent, and so on.

— In addition to this, according to Section 92 of the Patents Act, compulsory licences can also be issued 'suo motu' by the Controller of Patents pursuant to a notification issued by the Central Government if there is either a 'national emergency' or 'extreme urgency' or in cases of 'public non-commercial use'.

— India's only compulsory licence was granted to 'NATCO Pharma' in 2012 for 'Nexavar' drug (an anti-cancer drug) patented by 'Bayer' on satisfaction of all the three grounds set forth above.

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

— The Trade Marks Act, 1999 ('**Trade Marks Act**') is the main legislation.

— However, trademarks are afforded protection under several other laws including corporate laws and customs laws.

— There is no special protection accorded to trademarks of Lifescience products. However, the Supreme Court in one of its decision has held that Courts should apply a stricter test whilst dealing with trademark cases related to medicinal and pharmaceutical products.

— The Trade Marks Act provides protection to registered as well as certain protection to unregistered marks, under the tort of passing off.

— In a passing off suit, the burden of proof is on the Claimant.

— An Indian trademark affords protection for 10 years which can be renewed.

— Applications are made to the appropriate trademark office who will issue an examination report and arrange a hearing if necessary. If the trademark is accepted, it will be published in the official journal. Oppositions may be made prior to final registration.

— Average timeline from filing of a trademark application, to grant:

  - 18 to 24 months.

Are there any particular preclusions on Lifescience products branding? Any non-INN similar preclusions?

— The Controller General of Patents, Designs and Trade Marks has, on 7 February 2012, notified a list of International Non-Proprietary Names ('**INN**'), as declared by the World Health Organization ('**WHO**').

— The Trade Marks Act prohibits the registration of names of chemical elements or INNs which have been declared by the WHO and notified by the Registrar of Trade Marks.

— Any word which is identical with or deceptively similar to an INN is non-registrable under the Trade Marks Act.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— Unauthorised use of a mark which is identical with, or deceptively similar to the trademark that it is likely to cause confusion in the minds of the public, constitutes an infringement (subject to certain conditions).

— The burden of proof in an infringement suit is higher on the defendant.

— Remedies include:

- Injunction orders (interim as well as perpetual);
- Seizure orders; and
- Compensatory damages.

Data protection

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— In the Patent Act, there is no provision for data protection or data exclusivity for patent holders for medicines etc. However, the DC Rules provide that an inspector or drug regulator shall not without the sanction in writing of his official superiors, disclose any information acquired by him in the course of his official duties.

IP and competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

— Under the Competition Act, 2002, ('Competition Act') certain transactions meeting specified financial thresholds are required to be notified to the Competition Commission of India ('CCI') for approval.

— The provisions of Section 3(3) and 3(4) of the Competition Act pertain to agreements entered between enterprises restricting purchase/sale prices, curtailing supply/production of goods and services as well as entering exclusive supply/distribution arrangements and creating tie-in arrangements with the intention of adversely affecting the market. However, one of the exceptions in this regard is the reasonable protection of intellectual property rights.

— The Competition Act seeks to strike a balance between the exercise of intellectual property rights and concerns of anti-competitive agreements. The Competition Act allows for the imposition of 'reasonable conditions' for the protection of IPRs. The Act, however, does not provide any guidance regarding what conditions would stand the test of 'reasonability'.

— Thus, a fair amount of discretion has been left with the CCI to decide in specific cases if the conditions imposed to protect IPRs are reasonable or not.

— The pharmaceutical companies holding valid patents could enter into agreements with hospitals/pharmacists restricting prices if unregulated by the DPCO. Entry in the absence of generic drug manufacturers, as well as inter-se between pharmaceutical companies may lead to possible violations under the Competition Act.

— Any abuse of dominant position by the pharmaceutical companies e.g. delaying entry of generic medicines in the market and charging exorbitant prices in the guise of research and development costs may be in violation of the Competition Act.

— The Competition Act prohibits cartelisation. Pharmaceutical companies forming associations to exchange data and information serving purposes other than protection of the right holders could invite possible competition law violations.

— Recently, the CCI has fined the All India Organization of Chemists and Druggists for having indulged in anti-competitive activities including creating artificial restraints and barriers in the local market and causing inflation in the price of drugs. The CCI has also fined the Bengal Chemists and Druggists Association for concerting to fix trade margins by agreement amongst its members. While these come to the relief of the pharmaceutical industry at large, the CCI has also commenced a large-scale study of the pharmaceutical industry to gain market knowledge and identify any potential causes of concern. Further, pertinently, under the extant foreign direct investment policy of India, non-compete provisions are not permitted in investment agreements in the pharmaceuticals space except in special circumstances and with the specific approval of the Foreign Investment Promotion Board.

— Licence agreements involving the payment of royalty do not need to be registered with any authority. Further, royalty may be freely remitted to the foreign licensor under Indian exchange control regulations.

Indonesia

Patent

Describe your jurisdiction's patent system including application procedure, term of patent protection and average time from application to grant

Application procedure

— National registration

- Applicant applies directly to the Directorate General of Intellectual Property at the Ministry of Law and Human Rights ('DGIP') for patent registration.
- The DGIP will conduct an administrative examination.
- If accepted as a complete patent application, the application will be published (for potential opposition) in the Official Gazette of Intellectual Property.
- Upon request of the applicant the DGIP will conduct the substantive examination.

— International registration

- An applicant can file an international patent application through the PCT application.

Term of protection - since application date

- 10 (ten) years for utility model patent.
- 20 (twenty) years for invention patent.

Average time from application to grant

- 2 years for utility model patent.
- 5 years for invention patent.

Describe patentable and non-patentable subject matter within the lifesciences field

— Patentable subject matters

- A patent shall be granted to an invention that is novel, involves an inventive step, and is susceptible of industrial application.

— Non-patentable subject matters

- a method of examination, treatment, medication, and/or surgery applied to humans and/or animals;
- all living creatures, except micro-organisms;
- any biological process which is essential in producing plant or animal matter, except non-biological process or microbiological process.

Describe patent revocation/invalidation

— A patent can be revoked based on a below reason:

- the patent holder did not pay maintenance fees for 3 years in a row;
- by the initiative of the patent holder.

— A patent can also be invalidated by any of the below actions:

- opposed by a third party during the publication;
- a patent cancellation lawsuit initiated by a lawful party or the same patent holder;
- by initiative of a public attorney on the reason that the granting of a compulsory license is incapable of preventing the use of the patent in a form and way that prejudices the public interest within a period of 2 years counting from the date of the granting of the compulsory license or from the date of the granting of the first compulsory licenses in a situation where a number of compulsory licenses have been granted.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— A patent holder have the exclusive right to exploit the patent and prohibit any other party, who without consent cannot:

- in the case of a patent product: make, use, sell, import, rent out, deliver, or make available for sale or rental or delivery the patented product;
- in the case of a patent process: use the patented production process to make products and conduct other activities stated above.
- It is not considered patent infringement if the patent is used for the purpose of education, research, experiment or analysis, as long as it does not harm the normal interest of the patent holder.

— Claim for infringement

- A patent holder or a licensee is entitled to bring a lawsuit for damages in the Commercial Court against any party who deliberately and without rights performs any act that infringe the right of the patent holder or licensee.

— Available remedies

- Injunction;
- seeking compensation for damages or losses;
- declaring that a party has unlawfully infringed the patent of the authorized party;
- the Court can also order to seize, forfeit or destroy the infringing goods to prevent any possible further infringement.

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

Application procedure

— National registration

- applicant applies directly to the DGIP for trademark registration.
- the DGIP will conduct an formality examination and substantive examination.
- followed by publication (for potential opposition) for period of 3 months
- if there is no opposition the DGIP will issue a trademark certificate within 1 month from the end of publication period.

— Term of protection - from date of grant and can be renewed indefinitely

- 10 years

— Average time from application to grant

- 2-3 years

Are there any particular preclusions on Lifesciences products branding? Any non-INN similar preclusions?

Generally, there are no specific preclusions on the branding under the Trademark Law itself. However, there is a Government Regulation that provides specific restrictions for tobacco products branding.

- It is prohibited to use any sign or description on tobacco products that can mislead or encourage consumers.
- It is also prohibited to use the words Light, Ultra Light, Mild, Extra Mild, Low Tar, Slim, Special, Full Flavour, Premium or any other words that may indicate quality, superiority, sense of security, or personality, or any imagery that may invoke the same meaning.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— A trademark is infringed when the following occurs:

- Unauthorised use of a mark, which is similar in its entirety or in essence with a registered trademark and in such a manner that it causes confusion for the public, constitutes an infringement.

— Claim

- The trademark owner can take legal action against the infringing party by making a civil lawsuit for infringement in the commercial court.

— Remedies available include:

- Injunction;
- compensation for the profits gained;
- seeking damages for the loss suffered;
- stopping all acts of infringement;
- declaring that the infringing party has infringed the trademark.

Data Protection

Currently, there are no specific regulations or laws on data protection.

IP and competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

— Competition Law in Indonesia has become an integrated legal system under Law 5/1999 (Indonesia Competition Law or 'ICL'), which was followed by the establishment of *Komisi Pengawas Persaingan Usaha*, the Indonesian Competition Commission ('ICC').

— The ICL applies to any person, or business entity, either incorporated (having legal entity) or unincorporated, established and domiciled or engaged in activities in the Indonesian territory, either unilaterally or jointly through agreement, and operating business activities in the economic sector (referred to as 'undertaking'). The provisions under the ICL may accordingly likely extend to the Lifesciences sector.

— The ICC has the authority to proceed with investigations and adjudicate competition cases, examine agreements, business activities and/or actions performed by undertakings, impose administrative sanctions on undertakings proven guilty of violating the ICL, provide suggestions and considerations on government policies, and issue guidelines and/or publications in relation to the ICL.

— Substantive rules of the ICL are governed in Chapters 3 to 5, as follows:

- Prohibited agreements (among others, price fixing, price discrimination, resale price maintenance, market allocation, territorial restriction, boycott, tying and bundling);
- Prohibited activities (among others, monopolistic practices, market control, predatory pricing, bid-rigging);
- Abuse of dominant position (among others, restrictive trading terms, impeding potential competitor to enter market, interlocking directorship and cross ownership. Merger notification provisions are included in this chapter).

— In 2010, the ICC fined Pfizer entities and an Indonesian pharmaceutical company for allegedly having indulged in anti-competitive activities, including regulating the production and the pricing of their anti-hypertensive drugs, causing inflation in prices. Further, the ICL ordered to lower the prices of drugs each by 65% and 60%.

— Any merger, combination or share acquisition resulting in the assets or sales value of the merged entity exceeding a certain amount must be notified to the ICL no later than 30 working days after the completion of the transaction. Failing to comply may result in administrative sanctions.

— The ICL provides rules on exemption applicable to agreements relating to intellectual property rights such as licenses, patents, trademarks, copyright, industrial product design, integrated electronic circuits, trade secrets, and franchises. The ICC further regulates the IP exemption in its guidelines.

— Pursuant to the KPPU guidelines, an IP-related agreement must fulfil the following requirements to be exempted under this provision:exempted under this provision:

- Exemption must be applied only for issue that is not categorised as essential facilities;
- The agreement must be a licensing agreement related to IP rights;
- The agreement must fulfil all requirements as stipulated by prevailing regulations, e.g. registered in Indonesian IP authorities; and
- The agreement must not contain hard core anti-competition clauses.

Japan

Patents

The Patent Act protects inventions, which it defines as a 'highly advanced creation of technical ideas utilizing the laws of nature'. Patents are granted to the inventor of an invention with industrial applications after examination, provided the invention is not, prior to the filing of the patent application: (i) publicly known in Japan or a foreign country; (ii) publicly used in Japan or a foreign country; or (iii) described in a distributed publication, or made publicly available electronically in Japan or a foreign country. Patentability also requires novelty, and so patents are not granted where a person ordinarily skilled in the art of the invention would have been able to easily make the invention based on an invention prescribed in any of items (i) through (iii) above prior to the filing of the patent application. Japan is a member of the Patent Cooperation Treaty (PCT), which is intended to simplify the process for applicants seeking patent protection internationally for their inventions, helps patent offices with decisions on patents, and facilitates public access to a wealth of technical information relating to inventions going back to 1978.

Describe your jurisdiction's patent system including application procedure, term of patent protection and average time from application to grant

The procedure for obtaining a patent right is as follows; (i) Application to Japan Patent Office (JPO); (ii) Formality Examination (to be checked whether the necessary procedural and formal requirements are fulfilled); (iii) Publication (the contents of an application is published in the official gazette after 18 months have passed from the application date), (iv) Request for Examination (an examination will be carried out only when a request for examination is filed and the examination fees are paid; if there is no request within three years from filing date, the application will be regarded as withdrawn); (v) Substantive Examination (whether the claimed invention should be patented is examined); (vi) Decision to Grant a Patent/ Decision of Refusal (in the case of refusal, there are the processes of notification of reasons, appeal against the decision of refusal, an examination of the appeal and decision to grant/ decision of refusal); (vii) Registration (if a decision to grant a patent is made, the registration will be made, provided that the patent fee shall be paid for the registration) and (viii) Publication (the contents of the patent right will be published in the Patent Gazette).

According to the official information published by JPO, the average examination period for patent application is fifteen months in 2015 (this period is from Request for Examination to the Decision of Waiver, Withdrawal, or final decision to Grant a Patent/ Decision of Refusal excluding some cases.) In the case of Accelerated Examination, in which examinations can be started more rapidly than in normal examinations upon requests from the applicants under certain requirements, the average examination period shall be significantly shorter (average less than three months).

Describe patentable and non-patentable subject matter within the life science field

Medicine can be registered as a patent right, however, a patent right for the invention of a medicine initiate to be manufactured by mixing two or more medicines, etc. shall not be effective against the act of preparation of a medicine as is written in a prescription from a physician or a dentist and the medicine prepared as is written in a prescription from a physician or a dentist.

Patents may also be registered for cells, etc. used in genetic technology; in practice, patents have already been registered in relation to technology for production of iPS cells by Shinya Yamanaka, a Nobel Prize-winning professor.

Describe patent revocation/invalidation

The duration of a patent right is normally twenty years from the application date. However, an extension of the duration, up to five years, may be authorized by JPO in the case where a patent right could not be utilized after its registration for some period and the patent right is in the field of pharmaceuticals or agricultural chemicals.

In order to maintain patent rights, the periodical payment of patent fees is required. If patent fees are not paid, the patent right shall lose its effect.

There is a procedure of an opposition to a granted patent, which could be filed by any person only within six months from the date of publication of the Gazette containing the patent. Under the procedure of an opposition to a granted patent, administrative judges make a ruling that a patent related to an opposition to a granted patent is to be revoked, or that a patent related to an opposition to a granted patent is to be maintained. Where a revocation decision has become final and binding, the patent right shall be deemed never to have existed.

There is also a procedure of a trial for invalidation, which could be filed by interested persons at any time, even after the lapse of a patent right. Where a trial decision to the effect that a patent is to be invalidated has become final and binding, the patent right shall be deemed never to have existed.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Infringements can be either direct or indirect. With respect to direct infringement, the claimant must present evidence that all of the elements of the claim are satisfied in the accused product or method. According to the Patent Act, the scope of a patented invention is determined on the basis of the statements of the claim(s) and the meaning of the terms in a claim shall be interpreted in the light of the specification and the drawings attached to the application. Judges will also take into account the ordinary meaning, prosecution history, the state of the art at the time of filing the application and expert opinions. The doctrine of equivalents will supplement the missing elements under the limited conditions as specified by the Supreme Court. The conditions of the doctrine of equivalents are:

a) a claim element, which the subject product or method does not have, is not an essential part of the claimed invention;

b) the subject product or method must have the same object and effect as the claimed invention;

c) a person skilled in the art of the invention could have readily substituted the claimed element with the corresponding element in the subject product or method in view of the state of the art at the time of infringement;

d) the subject product or method must not be anticipated or obvious based on the prior art; and

e) the subject product or method was not intentionally excluded from the scope of the claim in the prosecution history.

Infringement may be indirect. The Patent Act provides that the manufacturing, assignment, or import of an item, which is used exclusively for manufacturing a patented product or using a patented method, is deemed to infringe the patent regardless of the awareness of the alleged infringer. In cases of the manufacturing, assignment or import of an item, which is used not only for manufacturing a patented product or using a patented method but also for other purposes, the patent holder must prove that the alleged infringer knows both of the existence of the patent and the fact the item can be used for manufacturing the patented product or using the patented method.

Trade Marks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

The Trademark Act protects registered trademarks used for specific products and/or services for a period of ten years, which is renewable. Any combination of characters, figures, signs, three-dimensional shapes, or combination thereof with colours, sound, motion pictures, holograms or position may be registered as a trademark if it is either: (i) used in connection with the goods of a person who produces, certifies or assigns such goods as a business; or (ii) used in connection with the services of a person who provides or certifies the services as a business.

However, excluded from the above are those that: (a) consist solely of a mark indicating, in a common manner, the common name of the goods or services; (b) are customarily used in connection with the goods or services; (c) consist solely of a mark indicating, in a common manner, in the case of goods, the place of origin, place of sale, quality, raw materials, efficacy, intended purpose, quantity, shape (including shape of packages), price, the method or time of production or use, or, in the case of services, the location of provision, quality, articles to be used in such provision, efficacy, intended purpose, quantity, modes, price or method or time of provision; (d) consist solely of a mark indicating, in a common manner, a common surname or name of a juridical person; (e) consist solely of a very simple and common mark; or (f) are, in addition to those listed in each of the preceding items, a mark by which consumers are not able to recognize the goods or services as those pertaining to the business of that particular person.

Japan is a member of the Madrid System, which is a one-stop solution for registering and managing marks worldwide since 2000.

In order to obtain a trademark right, an application for trademark registration with the Japan Patent Office must be filed. Japan adopts the first-to-file system in which the registration is granted to a person who has first filed an application, when an application for similar or identical trademark is filed, regardless of whether the trademark has been used previously. When an application for trademark registration is filed, the Japan Patent Office examines whether the trademark filed can be registered.

Trademarks which cannot be registered are as follows:

1. Any trademark used in connection with goods and services of an applicant that are not able to be distinguished from those of other persons

For example, trademarks which simply indicate the origin, place of sale and qualify of goods cannot be registered.

2. Trademarks against the public interest

For example a trademark which is identical with or similar to the national flag or likely to harm public order and morality (obscene or outrageous characters and figures, racist terms, etc.) cannot be registered.

3. Trademarks confusingly similar to trademarks of others

Once the trademark is registered, the right holder can exclusively use the registered trademark for designated goods or designated services. Moreover, it becomes possible to eliminate the use of any trademark similar to his own registered trademark by third parties for goods or services identical with designated goods or designated services and use of any trademark identical with or similar to his own registered trademark for goods or services similar to designated goods or designated services.

A request for injunction of infringement or a request for compensation for damage may be made against a person who infringes the right.

The term of trademark rights terminates ten years from the date of registration of establishment.

Are there any particular preclusions on life sciences products branding? Any non-INN similar preclusions?

According to the Act, the name of pharmaceuticals shall be described directly on the package of products. If the pharmaceuticals are listed in the Japanese Pharmacopoeia (JP), the names shall be the ones defined in the JP. If the pharmaceuticals are not listed in the JP and have nonproprietary names, the names shall be nonproprietary names. If the pharmaceuticals are not listed in the JP and do not have nonproprietary names, the names shall be the brand name approved by the authorization.

A similar concept of International Nonproprietary Name (INN) is the Japanese Accepted Name (JAN), which is the official non-proprietary or generic name given to a pharmaceutical substance. Although the names under INN and JAN were different in some cases, currently they are unified for naming.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

The right of trademarks is created by registration at the Patent Office under the Trademark Act. After the registration of a trademark, the holder of a trademark right has an exclusive right to use the registered trademark in connection with the designated goods or designated services. The holder of a trademark right or of exclusive right to use may demand a person who is infringing or is likely to infringe the trademark right or the exclusive right to use to stop or prevent such infringement. In making such a demand, the holder of a trademark right or of exclusive right to use may demand the person to take measures necessary for the prevention of such infringement, including the destruction of articles which constitute the act of infringement and the removal of equipment used for or contributing to the act of infringement. The holder of a trademark right or of exclusive right to use may claim against an infringer compensation for damage sustained as a result of the intentional or negligent infringement of the trademark right or the exclusive right to use, and there are presumptive rules for the protection of the holders of a trademark right or of exclusive right, such as the profits of the infringer is presumed as the damage of the holders.

Data protection

Data protection in relation to collecting and processing personal data in Japan is regulated under the Act on the Protection of Personal Information (the APPI) and subsidiary laws and related regulations and guidance. The Personal Information Protection Commission (PPC) has been delegated authority to issue guidelines for the implementation of the APPI and certain ministries have also issued guidelines with PPC for the implementation of the APPI for the industries they regulate (the Guidelines). The Guidelines are generally not enforceable but they are usually complied with.

Do data protection laws impact on pharmaceutical regulation in Japan?

The medical sector is subject to strict liability to protect personal information in Japan. There are five general Guidelines in relation to the APPI in health-related industries: (i) the Guideline to Handle Personal Information Properly for Medical and Nursing-Related Business Operators; (ii) the Guideline to Handle Personal Information Properly for Health Insurance Co-operations; (iii) the Guideline Regarding Safe Management of Medical Information Systems; (iv) the Guideline to Handle Personal Information for National Health Insurance Co-operations; and (v) the Guideline to Handle Personal Information Properly for Local Health Insurance Organisations.

The Guidelines require the protection of information relating to the deceased to the same level as that relating to a living individual, whereas the APPI only protects the personal information of living people.

The Guideline Regarding Safe Management of Medical Information Systems requires hospitals, clinics, pharmacies and midwives to provide safe and strict management of personal information with regard its collection, storage and processing.

MHLW and the Ministry of Economy, Trade and Industry (METI) require standards in health-related industries based on Health Level Seven (an international standard on message exchange), Digital Imaging and Communications in Medicine (an international standard on medical imaging and related reports) and other standards provided by the International Organisation for Standardisation (the ISO) and the Health Information and Communication Standards Board.

IP and Competition Law Issues

What is the competition law framework and how does it impact on the life science sector?

The Act on Prohibition of Private Monopolization and Maintenance of Fair Trade (AMA) is the main legislation which deals with competition law in Japan. The AMA prohibits three types of business activities: (i) Private Monopolization (business activities which excludes or controls the business activities of other enterprises thereby causing a substantial restraint of competition in any particular field of trade); (ii) Unreasonable Restraint of Trade (business activities in concert with other enterprises, mutually restrict or conduct their business activities thereby causing a substantial restraint of competition in any particular field of trade, such as cartels); and (iii) Unfair Trade Practices (business activities defined in Article 2 (9) of the AMA, such as concerted refusal and other refusal to trade, discriminatory consideration, and discriminatory treatment on trade terms, etc.).

As to the relation between competition law and IP rights, Article 21 of the AMA provides that the provisions of the AMA do not apply to acts found to constitute an exercise of rights under the Copyright Act, Patent Act, Utility Model Act, Design Act or Trademark Act. However, this exemption does not apply to all the uses of IP. The AMA will be applicable to the use of IP which is not essentially considered to be the exercise of the IP.

In order to specify how the AMA is applied to the exercise of intellectual property rights, the Japan Fair Trade Commission (JFTC) has issued three guidelines: (i) Guidelines Concerning Joint Research and Development under the Antimonopoly Act (1933), (ii) Guidelines on Standardization and Patent Pool Arrangements (2005), and (iii) Guidelines for the Use of Intellectual Property under the Antimonopoly Act (2007, amended 2016) (IP Guidelines).

The IP Guidelines provides that the AMA applies even to any case that it may seem, on its face, to be an exercise of rights if it cannot be recognized substantially as an exercise of a right, provided that it is found to deviate from or run counter to the intent and objectives of the intellectual property systems, which are, namely, to motivate entrepreneurs, to actualize their creative efforts and make use of technology, in view of the intent and manner of the act and its degree of impact on competition. Therefore, it is necessary to consider the applicability of this article carefully.

Bolar exception (safe harbor exemption)

The Patent Act provides that effects of a patent right do not extend to implementation of the patented invention for experimental or research purposes. The scope of implementation for "experimental or research" purposes is narrowly interpreted, that is, the subject matter of the experiment or research should be limited to that of the patented invention itself. Implementation of the patent right unrelated to the purpose of the Paten Act, that is, to encourage inventions and thereby to contribute to the development of industry, will constitute infringement of the Patent Act. For instance, implementation of a patented invention for test marketing or trial distribution of products which exploit the patented invention infringes the patent right. In the field of life science research, the Supreme Court found that an experimental implementation of a patented invention for the purpose of applying for the pharmaceutical approval to manufacture generic medicine does not infringe the patent right pursuant to this safe harbor exemption under Article 69 (1).

Parallel Importation

How are importations of pharmaceuticals, cosmetics or medical devices manufactured in foreign countries regulated under the Act?

In order to import pharmaceuticals, cosmetics or medical devices to Japan for business purposes, it is necessary to obtain prior approval or permission of the Minister of MHLW in accordance with the Act, and to pass required customs clearance procedure. An individual may import these products only for personal use under limited circumstances. In this regard, MHLW announces to the public that quality, effect and safety of pharmaceuticals, cosmetics or medical devices that are not being officially distributed in Japan in accordance with the Act, such as foreign manufactured products imported privately, are not examined, certified or ensured; therefore such products may cause significant health hazards.

How are foreign patents protected when the patented products are imported in Japan by way of parallel importation?

With respect to patent protection in case of parallel importation, the Supreme Court in Japan held that a patent holder who obtained patent rights in a foreign country cannot claim patent infringement in Japan against a transferee or its subsequent acquirer if such product had once transferred duly to the transferee outside of Japan, except where there was particular agreement between the patent holder and the transferee imposing limitation on sales destination etc. of the product and the agreement was explicitly indicated on the patent product itself. Accordingly, absent such explicit agreement and indication, parallel importations of foreign patented products to Japan by an importer who acquires the products in the course of legitimate process of business are not deemed to be infringement of foreign patent rights.

Compulsory license

How is the system of compulsory license of patent rights related to pharmaceuticals, cosmetics or medical devices operated in Japan?

Under the Patent Act, it is provided that "where the working of a patented invention is particularly necessary for the public interest, a person(s) intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license," and "where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Minister of Economy, Trade and Industry for an award." Patent rights vested in pharmaceuticals, cosmetics or medical devices regulated under the Act are not exempted from application of this "compulsory license" provision; therefore, technically speaking, in case where there is necessity of compulsory license for "public interest," the provisions may be applied to certain patent rights in order to deal with situations that may affect "public interest", e.g. in case of nationwide pandemics, etc. However, up to the present date, in Japan there has been no case where this has actually been invoked. It is specifically arguable that exactly when and how the provisions shall be applied to certain patent rights vested in pharmaceuticals, cosmetics or medical devices. While one questions effectiveness or promptness of the procedure, another argument is that application of the provision should be suppressive to protect proprietary rights of patent holders.

Korea

Patent

Describe your patent system including application procedure, term of patent protection and average time from application to grant

Application procedure

— National registration

- An applicant applies directly to the Korean Intellectual Property Office ('KIPO') for patent registration.
- KIPO will conduct an initial formalities examination of patent applications.
- Upon request of the applicant within 3 years of the filing date, KIPO will conduct the substantive examination.
- If accepted as a complete patent application, the application will be published (for potential opposition) in the official gazette for patents.
- Divisional applications can be filed within any of the following periods: (i) a period during which amendments can be made, (ii) within thirty (30) days from the date of service for a formal notice of rejection, or (iii) within three (3) months from the date of service of a notice of allowance.
- Before the registration, an applicant may amend the specification and claims (on limited grounds).
- After the registration, a patentee may file a separate patent correction trial to amend its patent. However, if there is a pending patent invalidation trial, a patentee can only file a motion to amend the patent within the pending patent invalidation trial, rather than filing a separate patent correction trial.

— International registration

- An applicant can file an international patent application through the PCT application.

Term of protection - since application date

- Ten (10) years for utility model patent
- Twenty (20) years for invention patent

Average time from application to grant

- Assuming that a request for examination is filed at the time of filing, 1.5 – 2 years for utility model patent and invention patent

Describe patentable and non-patentable subject matter within the Life Sciences field

— The below table contains typical patentable and non-patentable subject matter within the Life Sciences field:

Type	Subject	Patentability	Note
Substance	Genes (DNA sequences)	Patentable	Only if proven to be useful in, for example, identifying and diagnosing certain diseases
	Protein (sequence of amino acids)	Patentable	
	Microorganisms (e.g. virus, bacteria)	Patentable	A sample of the microorganism must be deposited
	Animal	Patentable Only if it is not against public order and morals	Manual of Animal-Related Patent Examining Procedure was recently published
	Part of the human body	Not Patentable	Any invention that offends or is contrary to human dignity is not patentable
Method/ process	Surgery, therapy methods	Method for treatment of the human body is not patentable Method for treatment of animals is patentable	Methods of medical treatment of the human body are conceived as essentially non-economic and have no commercial application
	Gene therapy method	Method for treatment of the human body is not patentable Method for treatment of animals is patentable	
	Diagnostic method	Method for treatment of the human body is not patentable Method for treatment of animals is patentable	
Others	A dosage regimen and a dose for medical use	Patentable	
	Inventions that are contrary to public order, morals, and health, or safety or general welfare	Not Patentable	

Describe patent revocation/invalidation/expiration

— A patent may be revoked if an applicant abandons its application during prosecution or fails to request examination within three (3) years from filing the application.

— A patent may be invalidated in the following circumstances:

  - An interested party or KIPO may initiate a patent invalidation trial; (a patent in the invalidation trial will be invalidated once the court decision is finalised); or
  - Once the notice of allowance is published, third parties have three (3) months to oppose registration of the patent.

— A patent may expire if a patent holder fails to pay maintenance fees within due dates for payment.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— Infringement

  - A patent is infringed when a third party makes, uses, sells, or offers for sale the patented invention as a business concern without a patentee's authorisation.
  - There are two typical patent infringement scenarios: direct and indirect infringement.
  - Under direct infringement, liability can be found when the patented invention is made, used, sold, or offered for sale either literally or under the doctrine of equivalents.
  - Under indirect infringement, liability can be found by an act of making, assigning, or importing a material used exclusively for producing the patented product or practicing the patented process.

— Claim for infringement

  - Patent infringement cases are brought before the five district courts (i.e. Seoul Central, Daejeon, Daegu, Busan, and Gwangju district courts), which have divisions in each court specialising in IP litigation. The Korean Patent Court has exclusive jurisdiction of an appeal from a final decision of the five district courts.

— Available Remedies

  - Injunction
  - Damages
  - Criminal penalties (i.e. imprisonment not exceeding seven (7) years or a fine not exceeding KRW 100 million), which are pursued by the public prosecutor upon filing of a complaint with the prosecutor

Other Patent-related Issues

— Patent-Drug Approval Linkage System ('**Linkage System**')

- The Linkage System refers to a system where approval of a generic drug by the MFDS (the Korean equivalent of the U.S. FDA) is linked to patents covering an original drug product. The Linkage System, which was introduced pursuant to the Korea-US Free Trade Agreement, is generally modeled after the U.S. Hatch Waxman regime, but there are some significant differences.
- A listing of patents covering an approved original drug is reviewed on a claim by claim basis by the MFDS and published online by the MFDS in the 'Green List,' which is equivalent to the 'Orange Book' published by the U.S. Food and Drug Administration.
- In order to effectively introduce the Linkage System, the Korean Pharmaceutical Affairs Act was amended to include the following process:

  (i) original drug companies submit to the MFDS a list of patents covering approved drugs for approval and publication by the MFDS on the Green List;

  (ii) when filing for marketing approval, a generic applicant must submit a certification for each patent listed on the Green List for an original drug of one of the following: that the patent has expired; the patent is not infringed; the patent is invalid; or the applicant obtained consent from the holder of the approved application and the patent owner; and

  (iii) a generic applicant must notify the holder of the approved application and the patent owner regarding the filing of a generic application, if the generic applicant has certified that the patent is invalid or will not be infringed by the generic drug for this application.
- The amended Korean Pharmaceutical Affairs Act also includes (i) a stay of the generic sales and (ii) generic exclusivity to the first generic that meets certain criteria.

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

— Application Process

- Korea is a first to file jurisdiction.
- A person can apply for registration of a trademark with KIPO.
- Unlike patent or utility model applications, trademark applications are automatically examined in order of their filing date.
- Once a person files a trademark application with KIPO, the usual examination process takes about 8 – 10 months.
- If an examiner rejects the application, the applicant is allowed to submit a request for re-examination.
- If the examiner finds no grounds of refusal, the application then is advertised for opposition for a period of two (2) months during which time period third parties may oppose registration. If no oppositions are filed or successfully contested, the application will be processed as a registration, subject to payment of registration fees.

— Term of Trademark protection

- An initial period of ten (10) years from date of grant.
- It may be renewed indefinitely subject to payment of renewal fees.

Are there any particular preclusions on Lifesciences products branding? Any non-INN (International Non-Proprietary Names) similar preclusions?

— The following trademarks may not be protected:

- A trademark that includes generic or genericised terms (e.g. aspirin);
- A trademark of a pharmaceutical product that directly describes quality, function, or effect of the pharmaceutical product. (e.g. 'pneumoshield,' which describes the function of treating a certain type of lung diseases);
- A trademark that is identical or confusingly similar to a notified INN on a non-distinctiveness ground.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— Infringement

- There are two typical actions for infringement of a registered trademark: (i) a person uses signage identical to a registered trademark in relation to either the registered or similar goods or services, and (ii) a person uses signage that is deceptively similar to a registered trademark in relation to either the registered or similar goods or services.
- For unregistered trademarks, complaints can be filed under the Unfair Competition and Trade Secret Act, which includes various additional legal causes of action, such as trade dress and a catch-all provision, which defines 'any other acts of using the achievements of other's substantial investment or efforts for one's own business without permission in a manner contrary to fair business practices or norms of competition' (Article 2(1)(j) of the UCPA).
- Trademark infringement cases are brought before the five district courts (i.e. Seoul Central, Daejeon, Daegu, Busan, and Gwangju district courts), which have divisions in each court specialising in IP litigation. The Korean Patent Court has exclusive jurisdiction of an appeal from a final decision of the five district courts.

— Available Remedies

- Injunction
- Damages
- Criminal penalties (i.e. imprisonment not exceeding seven (7) years or a fine not exceeding KRW 100 million), which are pursued by the public prosecutor upon filing of a complaint with the prosecutor

Data protection

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— Personal Information Protection Act ('**PIPA**')

- PIPA prohibits any public or private organisation from collecting and using personal information without the individual's consent.
- In particular, health information is classified as 'Sensitive Information.' PIPA requires an organisation using or managing Sensitive Information (i) to obtain a separate and specific consent from each individual, and (ii) to strictly follow the procedure set forth in PIPA and its enforcement decree in managing Sensitive Information. Other laws, e.g. the Medical Service Act, may waive the consent requirement or other restrictions on using Sensitive Information.

— The Bioethics and Safety Act ('**BSA**')

- BSA provides a legal framework in protecting personal information, including individual's genetic information and other personally identifiable information.
- BSA requires (i) a researcher to anonymise all personal information before providing such information to a third party, and (ii) an institution managing human biological materials to anonymise all personal information related to the human biological materials before receiving or providing any human biological materials to any third parties.

IP and Competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

— Monopoly Regulation and Fair Trade Act ('**MRFTA**')

- The MRFTA does not restrict legitimate exercise of IP rights (Article 59).
- However, with respect to the Life Sciences sector, the MRFTA prohibits pharmaceutical companies and wholesale drug distributors from engaging in unfair trade practices (e.g. resale price fixing and unfair solicitation of customers).

— The Korea Fair Trade Commission Guideline on Intellectual Property Rights Abuse ('**Guideline**')

- The Guideline prohibits unreasonable or unfair intellectual property right abuses with respect to the following: (i) granting a licence, (ii) creating patent pools and demanding cross-licences, (iii) exercising intellectual property rights in relation to standard technology, (iv) engaging in patent litigation, and (v) settling patent litigation.

— Reverse payment settlements

- A reverse payment settlement is a litigation settlement where an original drug manufacturer pays money (or provides other benefits) to a generic drug manufacturer in exchange for market withdrawal or delayed entry of the generic.
- In Korea, a reverse payment settlement constitutes an unfair settlement of patent litigation and thus is illegal. Accordingly, both an original drug manufacturer and a generic drug manufacturer may be liable to the National Health Insurance Service for damages caused by a reverse payment settlement.
- All agreements settling patent litigation with respect to approved drugs on the Green List between an original drug manufacturer and a generic drug manufacturer must be reported to the Korean Fair Trade Commission (Article 69-3 of the Korean Pharmaceutical Affairs Act).

Singapore

Patents

Describe your patent system including application procedure, term of patent protection and average time from application to grant

Application Procedure

— National registration

- File application to the Intellectual Property Office of Singapore ('IPOS') which conducts Preliminary Examination and issues Clear Formalities Report.
- After IPOS publish patent application, applicant can request for search and examination.
- After IPOS issues a notice of eligibility subsequent to the Report containing results of search and examination process reflect that there is no unresolved objection to the registration, applicant can request for issuance of the Certificate of Grant.

— International registration

- An applicant (who is a resident or national of Singapore) can file an international application under the Patent Cooperation Treaty ('PCT') directly.

— **Term of protection - since application date**

- 20 years from the Date of Filing, which is obtained from the IPOS after the IPOS determines that all the necessary conditions for a patent application have been satisfied.

— **Average time from application to grant**

- 2-4 years

Describe patentable and non-patentable subject matter within the Life Sciences field

— **Patentable subject matters:**

- To be patentable, an invention must be new, possess an inventive step and be capable of industrial application.
- For example, genetic engineering patents (isolated DNA sequences), microbiological process patents, patents of chemical or pharmaceutical compounds, medical sciences patents.

— **Non-patentable subject matters:**

- Method for the treatment of the human or animal body by surgery or therapy.
- Diagnosis practised on the human or animal body.
- Invention that could encourage offensive, immoral or anti-social behaviour.

Describe patent revocation/invalidation

— Any person may apply to revoke a patent for an invention on any of the grounds set out in s80 of the Patents Act.

— The procedure on application for revocation, commences with the filing of Patents Form 35 (PF 35) with a fee of S$500 accompanied by a statement setting out fully the grounds of revocation including the facts on which the applicant relies and the relief which he seeks.

— Within three months from the receipt of an application for revocation of a patent, the proprietor may file a counter-statement that states the grounds on which he contests the application for revocation.

— At the same time when the proprietor files the counter-statement referred to above, he may also file an application to amend the specifications of the patent.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— A patent is infringed when someone does the following without the consent of the patent owner:

- Makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
- Uses the process or offers it for use in Singapore when he knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent;
- Disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

— **Claim for infringement**

- The patent owner can take legal action against the infringing party by making a civil application for infringement to the court.

— **Available remedies**

- Injunction.
- Demanding for the profits gained.
- Seeking damages for the loss suffered.
- An order for the infringing party to deliver up or destroy any patented product in relation to which the patent is infringed.
- Declaration that the infringing party has infringed the patent.

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

Application Procedure

— **National registration**

- The applicant should conduct a thorough search of existing trademarks and file application to IPOS who will examine and publish the trademark.
- If there is no opposition, a Certificate of Registration will be issued.

— **International registration (Madrid System)**

- The applicant can file an international trademark application under the Madrid Protocol.

— **Term of protection - from date of grant and can be renewed indefinitely**

- 10 years

— **Average time from application to grant**

- 6 to 18 months

Are there any particular preclusions on Life Science products branding? Any non-INN similar preclusions?

— Generally, there are no industry specific preclusions on the registration of trademarks. The only requirements for a trademark to be registered are that:

- The mark must be a sign capable of being represented graphically;
- The mark must have distinctive character; and
- The mark must not be contrary to public policy or morality.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— A trademark is infringed when the following occurs:

- An identical mark has been used in relation to identical or similar goods or services.
- A similar mark has been used in relation to identical or similar goods or services resulting in confusion for the public.
- A similar mark to a registered well-known mark on goods or services that are dissimilar to those registered with the well-known mark (if there is a likelihood of confusion or connection to the well-known mark, and possible damage to the interests of the owner).

— **Claim**

- A civil application for infringement is made to the court.

— **Remedies available include:**

- Injunction.
- Demand for the profits.
- Seeking damages for the loss suffered.
- Statutory damages.
- Erasure of the offending sign.
- Delivery up of infringing goods.
- Disposal of the infringing goods.

Data protection

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— The Personal Data Protection Act 2012 ('PDPA') provides that an organisation cannot collect, use or disclose an individual's personal data without their consent.

— The operation of clinical trials will require the consent of participants for personal data to be collected and obtained. The added obligations regarding the care, protection, retention and transfer of personal data will impose an additional burden on those conducting clinical trials.

— Human biological data would potentially fall under the definition of 'personal data' under the PDPA, and thus, future regulations regarding human biomedical research will have to be mindful of the obligations imposed by the PDPA.

— The PDPA does provide certain exceptions in Schedule 2 to the PDPA to the obligations above, of which the exception allowing for the use and disclosure of personal data without first seeking an individual's consent for research and evaluative purposes may apply to the pharmaceutical industry.

IP and competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

Competition Authorities and their Regulatory Powers

— The key legislation governing competition is the Competition Act 2004, and its provisions extend to any person or legal person and all industries, including the Lifesciences sector.

— The main competition regulatory activity in Singapore is the Competition Commission of Singapore ('CCS') whose duties include providing guidance on competition law issues, investigation of breaches of competition law, adjudicating in competition cases etc. CCS decisions have the force of common law. The CCS also has the power to administer fines and jail terms for violations of the Competition Act.

— The 3 main activities prohibited under the Competition Act are:

- Anti-competitive agreements, decisions and practices (Section 34 Prohibition);
- Abuse of a dominant position (Section 47 Prohibition); and
- Mergers which substantially lessen competition (Section 54 Prohibition).

— Investigations by the CCS:

- Proposed merger/acquisition or agreement which may potentially infringe the Competition Act.
- Complaint by a member of public regarding anti-competitive behaviour.

Proposed merger between GSK and UCB SA (2009)

Issue

— Whether the proposed merger between the two companies would lead to reduced market competition, by way of their horizontal overlap in supply of certain pharmaceutical products.

— Competition concerns arose (according to CCS guidelines) since for certain drugs, the merged entity had more than 40% market share and the post-merger concentration ratio of 3 biggest firms in the market) was 70% or more.

Outcome

— Non-coordinated

  - As regards RCA drugs, parties' market share in the product category did not cross the indicative threshold of the CCS guidelines.
  - As regards R1B drugs, even if there was a pre-merger horizontal overlap, competitors were still providing generics and substitutes.

— Coordinated

  - Any risks of coordinated behaviour were mitigated by low barriers to entry and countervailing buyer power.
  - Large buyers undertake annual tenders leading to aggressive bidding and lower prices, thereby leading to the destabilising of any coordinated behaviour.

Conclusion

— Competition Act was not infringed upon.

Proposed acquisition by Parkway of Radlink (Oct 2014)

Issue

— Overlapping goods and services including radiology and imaging, primary care clinics and supply of radiopharmaceutical, raised possible issues relating to infringement of the Competition Act.

— Following a Phase 2 review, the CCS announced in March 2015 a provisional decision to prohibit the proposed acquisition. This is a first by the CCS. This comes after the CCS was unable to conclude during a Phase 1 review that the proposed transaction would not result in a Substantial Lessening of Competition.

Taiwan

Patents

Describe your jurisdiction's patent system including application procedure, term of patent protection and average time from application to grant

Application Procedure

— Invention patent and design patent: Substantive examination is required. Requests for substantive examination shall be made by any person within the 3 years after the filing date of the patent application, or the application will be deemed to have been withdrawn. The patent will only be published after the applicant has paid the patent certificate fee and the first-year patent annuity within 3 months of the approval decision.

— Utility model patent: Only a formality examination is required.

Term of protection

— Invention patent: 20 years from the filing date.

— Utility model patent: 10 years from the filing date.

— Design patent: 12 years from the filing date.

Average time from application to grant

— Invention patent: According to the 2017 statistics released by the Taiwan Intellectual Property Office (TIPO), the average time of filing the first OA is approximately 9 months, and the average time to grant a patent is approximately 16 months.

— Utility model patent: About 4 to 6 months, according to the processing period sheets of the patent.

— Design patent: About 10 to 12 months, according to the processing period sheets of the patent.

Describe patentable and non-patentable subject matter within the life sciences field

Non-patentable subject matter in the life sciences field includes the following:

— Animals, plants, and essential biological processes for the production of animals or plants. However an exception is the process for producing microorganisms; these are patentable. While plants are not patentable under the Patent Act, breeders can file applications for a plant variety right in accordance with the Plant Variety and Plant Seed Act.

— Diagnostic, therapeutic or surgical methods for the treatment of humans or animals.

Describe patent revocation/invalidation

Extinguishment of the patent right

— The patent will extinguish; when the term of protection expires, if a patentee passes away without heirs, if a patentee abandons his or her right, or if the annuity fee is not paid up.

Administrative procedure

— Anyone can submit a request for invalidation to the TIPO if a patent violates any requirement of patentability. The patentee will be required to provide a response within 1 month or an approved period. If the invalidation action is thought to be well grounded, the TIPO will decide to revoke the patent. The patentee needs to file a proceeding for an administrative remedy, or the patent will be deemed to be void from the beginning.

Litigation

— Besides administrative remedy proceedings, patent invalidation can also be judged in civil litigation if there is a pending patent infringement case. The judgment made in a patent infringement litigation is not final. Thus the patent will not be extinguished, but it will be deemed void in that specific patent infringement case.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— The patentee has an exclusive right to prevent others from exploiting the invention without his or her consent, unless the other person's act falls into one of the specific circumstances indicated in Article 59 of the Patent Act. For example, the research exemption. For patent infringement cases, the civil court will be in charge of the claim construction. They will interpret and determine the scope of the claims by referring to the intrinsic evidence (including the description, drawings and filing history) and the extrinsic evidence (including prior art, textbooks or dictionaries). When the scope of the claims is determined, the court will compare the allegedly infringing product with the scope of the claims, one by one, following the All-element Rules. If not all the elements are present in the allegedly infringing product, the court shall adopt the Doctrine of Equivalents and will be subject to its limitations, such as estoppel and the prior art defence.

— The Patent Act provides a patentee with the right to demand that a person who is infringing, or who is likely to infringe the patent right, to stop or prevent such infringement. The patentee may request the destruction of the infringing products. If an infringer knowingly, or with reasonable grounds to know, commits an infringement, the patentee can claim damages for the infringement.

Trade Marks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

Application procedure

— The Trademark Act adopts the registration protection system; only granting the exclusive rights to applicants after registration, and regardless of whether the signs have been used before registration. Any sign with distinctiveness can be registered as a trademark; thus, the following would be excluded: (a) a sign consisting exclusively of a description of the quality, intended purpose, material, place of origin, or relevant characteristics of the designated goods or services; (b) a sign consisting exclusively of the generic mark or term for the designated goods or services. In addition, a trademark cannot be registered if it violates Paragraph 1, Article 30 of the Trademark Act, including but not limited to (a) being identical with, or similar to, another person's registered trademark, or earlier filed trademark, and to be applied for goods or services identical with, or similar to, those for which the registered trademark is protected or the earlier filed trademark is designated, and hence there exists a likelihood of confusion of relevant consumers; (b) being identical with or similar to another person's well-known trademark or mark, and hence there exists a likelihood of confusion of the relevant public or the likelihood of dilution of the distinctiveness or reputation of the said well-known trademark or mark; and (c) being identical with, or similar to, another person's earlier used trademark, and to be applied for goods or services identical with, or similar to, those for which the earlier used trademark is applied, where the applicant with the intent to imitate the earlier used trademark, being aware of the existence of the earlier used trademark due to contractual, regional, or business connections, or any other relationship with the proprietor of the earlier used trademark, files the application for registration.

Term of trademark protection

— 10 years from the date of publication for registration.

Average time from application to grant

— According to the 2017 statistics released by the TIPO, the average time of filing the first OA is approximately 5 months, and the average time to grant a trademark right is approximately 7 months.

Is there any particular preclusion on life sciences products' branding? Any non-INN similar preclusion?

— The Trademark Act does not have any specific restrictions on life sciences products' branding. Though names for pharmaceutical substances can be prohibited from registration if they are deemed as a generic mark that is lacking in distinctiveness.
— Currently there is no non-INN similar preclusion in Taiwan.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— The core of a trademark is its distinctiveness; thus, any conduct without the consent of the right holder and in the course of trade will constitute a trademark infringement as follows:
(a) using a trademark which is identical with the registered trademark, and used in relation to goods or services which are identical with those for which it is registered;
(b) using a trademark which is identical with the registered trademark, and used in relation to goods or services similar to those for which the registered one is designated, and hence there exists a likelihood of confusion of relevant consumers;
(c) using a trademark which is similar to the registered trademark, and used in relation to goods or services identical with, or similar to, those for which the registered one is designated, and hence there exists a likelihood of confusion of relevant consumers.
The Trademark Act provides the right holder with the right to demand that a person who infringes, or is likely to infringe the trademark right stops or prevents such infringement. The right holder may request the destruction of the infringing products.
The right holder can claim damages for infringement if an infringer who knowingly, or with reasonable grounds to know, commits an infringement.

— As for well-known registered trademarks, any conduct without the consent of right holder that consists of knowingly using a trademark which is identical with, or similar to, another person's well-known registered trademark, and hence that there exists a likelihood of dilution of the distinctiveness or reputation of the said well-known trademark, will be deemed as trademark infringement.

— Trademark infringement can lead to criminal liability pursuant to Articles 95-97 of the Trademark Act.

Data protection

Do data protection laws impact on pharmaceutical regulation in Taiwan?

— Collecting, processing or using the personal information of: medical records, medical treatments, genetic information, or health examinations is generally prohibited under the Personal Information Protection Act; unless it is necessary for a government agency or an academic research institution to perform statistical or other academic research for the purposes of medical treatments, public health, or crime prevention. After its processing by a provider, or its disclosure by a collector, the information must not lead to the identification of a specific person.

— The FDA can designate medical care institutions to set up a plan of security measures for the personal information file, or to set up disposal measures for the personal information after the termination of business. The draft of the Regulations Governing Personal Information File Security Maintenance Plan for the Nursing Care Institutions was publicly announced in 2017, but has not yet come into force.

IP and Competition Law Issues

What is the competition law framework and how does it impact on the life sciences sector?

— The main legislation on competition law in Taiwan is the Fair Trade Act, which can be divided into "restraint on competition" and "unfair competition". The former focuses on prohibiting an enterprise from abusing its market power, including limitations on monopolies, mergers, and concerted actions. The latter mainly regulates the deceptive or obviously unfair conduct that may affect trading orders. This forbidden conduct includes any conduct that would constitute the imposure of restrictions on the resale prices of goods; false or misleading advertising or descriptions on products that are sufficient to affect trading decisions; or disseminating any false statements that may lead to the derogation of the reputation of another enterprise.

— In the life sciences sector, pharmaceutical firms need to be aware of, among others, not violating the regulation on false or misleading advertising, as publicising the efficacy of pharmaceuticals usually falls into the violation of exaggerated medicament advertisements. In addition, the Fair Trade Commission recently made the decision to fine one pharmaceutical firm based on the fact that it imposed restrictions on contracted pharmacies on the resale prices of drugs.

Bolar exception

— Any conduct necessary for exploiting the invention for the purpose of research or experiments will not be regarded as patent infringement. The research exemption is not limited to exploitation for non-profit purposes, but the necessary conduct should be directly related to research or trials. This includes any conduct of making, offering for sale, selling, using, or importing the product for the aforementioned purposes. In the life sciences sector, the Patent Act also provides an exemption for any conduct directly related to research or trials that is necessary for obtaining registrations and market approvals under the Pharmaceutical Affairs Act or for obtaining market approvals from other foreign countries. The scope of market approvals covers new drugs, generic drugs, and medical devices. The scope of necessary conduct includes, but is not limited to, pre-clinical trials, research, and clinical trials.

Compulsory licence

How is the system of compulsory licensing of patent rights relating to pharmaceuticals, cosmetics or medical devices operated in Taiwan?

— To assist countries that have insufficient or no manufacturing capacities in pharmaceuticals in obtaining pharmaceutical products needed for treating epidemics (including HIV/AIDS, tuberculosis, and malaria), an applicant can submit a request to the TIPO for a compulsory licence to exploit a patent. The request for the compulsory licence may only be granted if the requestor has made efforts to obtain authorisation from the right holder, on reasonable commercial terms and conditions, and these efforts have not been successful within a reasonable period of time. However, the above shall not apply if the compulsory licensing of the required pharmaceutical product(s) has been granted in the importing country. The approved applicant shall be subject to certain restrictions, including only being allowed to export to relevant countries; limitations on the manufacturing quantities; and the paying of appropriate remuneration. The competent health and welfare authority granted a compulsory licence of "Tamiflu" in 2005; "Tamiflu" was granted for the purpose of a national emergency in accordance with the general clauses of a patent compulsory licence.

Thailand

Patents

Describe your patent system including application procedure, term of patent protection and average time from application to grant

— **Application procedure**

- Thailand is a signatory to the Patent Cooperation Treaty ('PCT').
- Patent applications should be made to the Patent Office of the Department of Intellectual Property ('DIP').
- A preliminary examination is conducted and the patent application is then published in the official Patent Journal.
- A substantive review is undertaken after publication. The publication and substantive review process can take several years (or more if objection is made to the patent).
- Guidance on the application procedure and fees are found on this website (in both Thai and English): www.ipthailand.go.th/ipthailand.

— **Term of protection**

- 20 years from the date of filing the application in the country.
- No extensions or renewals are allowed.

— **Average time from application to grant**

- The entire process for issuance of an invention patent can take from eight to ten years.

Describe patentable and non-patentable subject matter within the Lifesciences field

— **Patentable subject matter**

- Polymorphic forms (such as solvates or different crystalline forms of a known chemical compound).
- Formulations (that is, pharmaceutical compositions).
- New therapeutic use of a known chemical compound.
- Combination and dosage form.
- Methods for preparing medicinal products or related substances.

— **Non-patentable subject matter**

- Micro-organisms that naturally exist and their components, animals, plants or extracts from animals or plants.
- Scientific and mathematical rules and theories.
- Computer programs.
- Inventions that are contrary to public order or morality, public health or welfare.
- Methods for diagnosing, treating or curing human or animal diseases.

Describe patent revocation/invalidation

— The validity of patents can be challenged in the Intellectual Property and International Trade Court (IP & IT Court), which can revoke a patent.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

— **Claim and remedies**

- Infringement of exclusivity may be enforced through either civil or criminal action in the IP & IT Court.
- Civil remedies include injunctive relief and damages.
- Criminal penalties can include imprisonment not exceeding two years or a fine not exceeding THB 400,000, or both.

— **How is a patent infringed?**

Infringement can be divided into two categories: direct and indirect infringement.

– **Direct infringement:** Section 36 of the Patent Act establishes the acts that constitute direct patent infringement. A distinction must be made between product and process patents:

- **Products:** the act of producing, using, selling, possessing for sale, offering for sale, or importing into Thailand constitutes infringement.
- **Processes:** it is forbidden to use the process stated in the patent, produce, use, sell, possess for sale, offer for sale, or import into Thailand.
- **Statutory exemptions** exist in Section 36 Paragraph 2(2).

– **Indirect (contributory) infringement:** Section 84 of the Penal Code.

Trademarks

Describe your jurisdiction's trademark system including application procedure, term of trademark protection and average time from application to grant

— A trademark may be registered if it meets the following conditions:

- It is distinctive.
- It is not forbidden under the Trade Mark Act.
- It is not identical or similar to trademarks registered by others.

— **Application procedure**

- Applications are made to the Trade Mark Office of the DIP.
- One trademark or service mark application can be filed per class. Multiple class applications are not available.
- Guidance on the application procedure is available on this website (in Thai only): www.ipthailand.go.th

— **Average time from application to grant**

- 12 months

— **Duration of trademark protection**

- 10 years from the filing date.
- Can be renewed every 10 years.
- The application for renewal must be filed within 90 days of a trademark's expiry date from the original registration or from the date of the previous renewal.
- Therefore, provided that the correct procedure is completed, a trademark can be indefinitely renewed.

Are there any particular preclusions on Lifescience products branding? Any non-INN similar preclusions?

— Sections 88 to 90 of the Drug Act regulate the advertising of medicinal products and are enforced by the FDA.

— The authorities also take the Consumer Protection Act 1979 into consideration when regulating advertising practice.

— In 2000, Notification No. 5 of the Ministry of Commerce was implemented, which also prohibits the registration of a mark that is identical or similar to an INN; however, there have been only a few cases regarding its enforcement.

— The registration of a mark that is identical or similar to an INN designated by the WHO is forbidden by the Thai Intellectual Property and International Trade Court.

— The court has stated that the similarity between such marks and the INN were likely to cause confusion and the use of such a mark creates an unjust advantage that leads to unfair competition.

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— Section 44 of the Trade Mark Act provides the trademark owner with the exclusive right to use the goods for which registration has been granted. Hence, a trademark is infringed when it is used by someone other than the trademark owner.

— Claim and remedies

- Infringement of exclusivity may be enforced through either civil or criminal action in the IP & IT Court.
- Civil remedies can issue injunctive relief and damages.
- Criminal penalties can include imprisonment not exceeding four years or a fine not exceeding THB 400,000, or both.

Data Protection

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— The Trade Secrets Act 2002 contains a legal framework for the protection of trade secrets and other confidential information. The unauthorised use and disclosure of such information is an actionable offence, punishable by civil and criminal remedies.

— A limited form of data protection is provided under the trade secrets law in relation to data submitted to the Thai FDA. The submitted data or information, either in whole or in part, may amount to a trade secret in the form of a testing result, or other information regarding its preparation, discovery, or creation. In this case, the owner has the right to request that the FDA maintain the confidentiality of the data submitted.

— The FDA will keep data confidential for five years from the date that it is notified that the data is to be treated as a trade secret.

— The FDA will only keep the data confidential while it can still rely on the data to assess and approve a subsequent generic application.

— Thailand does not have a unified and dedicated statute which confers a clear right of data privacy.

— However, there are other laws that would allow for relief if the use of data or information causes damage to reputation, health, or property of the information owner/subject.

IP & competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

— Competition law is governed by the Trade Competition Act (1999) (Trade Competition Act).

— The main issues covered by the Trade Competition Act include:

- Abuse of Dominance.
- Merger Control.
- Collusion and Price Fixing.
- Unfair Trade.
- Agreements between domestic and international business.

— Business operators in Thailand are prohibited from colluding with overseas business operators in a manner which restricts the ability of residents in Thailand from purchasing goods directly from businesses overseas.

— There are very few investigations concerning pharmaceutical products. There have been no competition, abuse of dominance or parallel import cases brought to the Trade Competition Committee or before the Court relating to the generic entry of pharmaceuticals.

— There is no requirement for a patent or trademark licence (and payment of royalties under it to a foreign licensor) to be approved or accepted by the Government or any regulatory body. However, a patent or trademark licence agreement must be recorded with the Department of Intellectual Property to be enforceable.

— Compulsory Licences

  • The Ministry of Public Health has issued compulsory licences for seven drugs between 2006 and 2008.

  • The Minister of Health claims that the Thai Government is mandated to achieve universal access to essential medicines under the National Health Security Act B.E. 2545 (2001).

  • The Government reserves the right to use patents in situations of 'vital importance,' as stated in Section 51 of the Patent Act B.E. 2522 (1979) and in accordance with the TRIPS agreement, Doha Ministerial Declaration on the Trips Agreement and Public Health 2001.

  • The legitimacy of these licences has been extensively debated and remains a controversial topic.

Vietnam

Patents

Describe your patent system including application procedure, term of patent protection and average time from application to grant

— At present, there are two types of patents in Vietnam:

  - Invention patents and utility solution patents.

— Both types are granted on an invention or a group of inventions which fulfil the unity requirements.

— There are three patent application types in Vietnam:

  - First filed patent application;
  - Patent application claiming priority under the Paris Convention; and
  - Patent Cooperation Treaty (PCT) application.

— **Application Procedures**

  - Patent application dossier is filed at the National Office of Intellectual Property (NOIP) and is given a filing date and application number.
  - The application will be published in the Industrial Property Gazette and then be substantively examined.
  - If the substantive examination results are positive, the NOIP will issue an invitation to pay the granting fee.
  - In practice, there may be many further office actions.

— Guidance on the application procedure for patent registration is provided on the NOIP website in Vietnamese (www.noip.gov.vn).

Describe patentable and non-patentable subject matter within the Lifesciences field

— **Non-patentable subject matter**

- Discoveries, scientific theories;
- Mathematical methods;
- Schemes, plans, rules and methods for performing mental acts, training domestic animals, playing games, doing business;
- Computer programs;
- Presentations of information;
- Aesthetic solutions;
- Plant varieties, animal varieties;
- Processes of essentially biological processes for the production of plants and animals except microbiological processes;
- Prevention, diagnostic and therapy methods for treatment of the human or animal body.

Describe patent revocation/invalidation

— A patent can be entirely revoked if the:

- applicant has no right to registration;
- has not been assigned such a right; and
- the invention in the patent does not satisfy the protection requirements at the grant date of the patent.

— A patent can be partially revoked if it in part fails to satisfy the protection requirements.

— In addition, a patent can be terminated in the following cases:

- If the owner has not paid the annuities for maintenance as prescribed.
- If the owner relinquishes the rights conferred by the patent.
- If the owner no longer exists.

— The patent holder can request termination of the use right where the grounds for compulsory licensing no longer exist and are unlikely to recur, provided that such termination is not prejudicial to the licensee.

How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

— A patent is infringed by the use of a protected product or process or a product or process identical or equivalent to such protected product or process during the term of its patent, without permission of the patent holder or a competent authority.

Claims

— Administrative action: filing a complaint with customs and/or the Inspectorate specialised in Science and Technology such as the Inspectorate of the Ministry of Science and Technology.
— Court action.

Civil remedies

— Compulsory termination of the act of infringement of intellectual property rights;
— Compulsory public rectification and apology;
— Compulsory performance of civil obligations;
— Compulsory compensation for damages; and
— Compulsory destruction or distribution or put to use for non-commercial purposes.

Administrative remedies

— Compulsory termination of the infringing acts;
— Warning or monetary fine;
— Compulsory destruction of the infringing elements; and
— Suspension for a limited term of relevant business activities.

Trademarks

Describe your trademark system including application procedure, term of trademark protection and average time from application to grant

— Application Procedures

- A national trademark registration dossier is filed at the NOIP.
- The application will be published in the Industrial Property Gazette.
- The NOIP will examine the availability of registration of the applied mark.
- If the trademark meets all required criteria of protection, the NOIP will issue a Notification of Granting Certificate and request the applicant to pay the registration fee within one month.
- After these fees are paid, a certificate of trademark registration will be issued.
- Note: Guidance on the application procedure for trademark registration is provided on the NOIP website in Vietnamese (www.noip.gov.vn).

How is a trademark infringed? How is a claim for trademark infringement made and what remedies are available?

— The use of signs 'confusingly similar or identical to a protected trademark for the same or similar goods/services' during the valid term of a trademark without permission of the owner is an infringement of the trademark.

Claim and remedies

— The claims and remedies are the same as for patent infringement as described above.

— In addition, trademark infringement could be subject to criminal charges.

Is there any particular preclusion on Lifescience products branding? Any non-INN similar preclusions?

The preclusions on a trademark of a product, not only limited to Lifesciences products, are below:

– *Signs ineligible* for protection as marks.

The following signs shall be ineligible for protection as marks:

1. Signs identical to or confusingly similar to national flags or national emblems.
2. Signs identical to or confusingly similar to emblems, flags, armorial bearings, abbreviated names or full names of Vietnamese State bodies, political organisations, socio-political organisations, socio-politico-professional organisations, social organisations, socio-professional organisations or international organisations, unless permitted by such bodies or organisations.
3. Signs identical to or confusingly similar to real names, aliases, pseudonyms or images of leaders, national heroes or famous personalities of Vietnam or foreign countries.
4. Signs identical to or confusingly similar to certification seals, check seals or warranty seals of international organisations which require that their signs must not be used, unless such seals are registered as certification marks by such organisations.
5. Signs which cause misunderstanding or confusion or which deceive consumers as to the origin, properties, use, quality, value or other characteristics of goods or services.

– *Distinctiveness of* marks.

1. A mark shall be deemed to be distinctive if it consists of one or more easily noticeable and memorable elements, or of many elements forming an easily noticeable and memorable combination, and does not fall into the cases stipulated in clause 2 of this article.

2. A mark shall be deemed to be indistinctive if it is a sign falling into one of the following categories:

— Simple shapes and geometric figures, numerals and letters or scripts of uncommon languages, except where such sign has been widely used and recognised as a mark;

— Conventional signs or symbols, pictures or common names in any language of goods or services that have been widely and regularly used and known to many people;

— Signs indicating time, place and method of production; category, quantity, quality, properties, ingredients, use, value or other characteristics descriptive of goods or services, except where such sign has acquired distinctiveness by use before the filing of the application for registration of the mark;

— Signs describing the legal status and business sector of business entities;

— Signs indicating the geographical origin of goods or services, except where such sign has been widely used and recognised as a mark or registered as a collective mark or certification mark;

— Signs other than integrated marks which are identical or confusingly similar to registered marks of identical or similar goods or services on the basis of applications for registration with earlier filing dates or priority dates, as applicable, including applications for registration of marks filed pursuant to a treaty of which the Socialist Republic of Vietnam is a member;

— Signs identical or confusingly similar to another person's mark which has been widely used and recognised for similar or identical goods or services before the filing date or the priority date, as applicable;

— Signs identical or confusingly similar to another person's mark which has been registered for identical or similar goods or services, the registration certificate of which has been invalidated for no more than five years, except where the ground for such invalidation was non-use of the mark;

— Signs identical or confusingly similar to another person's mark recognised as a well-known mark which has been registered for goods or services which are identical with or similar to those bearing such well known mark, or for dissimilar goods or services if the use of such mark may affect the distinctiveness of the well known mark or the mark registration was aimed at taking advantage of the reputation of the well known mark;

— Signs identical or similar to another person's trade name currently in use if the use of such sign may cause confusion to consumers as to the origin of goods or services;

— Signs identical or similar to a protected geographical indication if the use of such sign may mislead consumers as to the geographical origin of goods;

— Signs identical to containing or being translated or transcribed from protected geographical indications for wines or spirits if such sign has been registered for use with respect to wines and spirits not originating from the geographical areas bearing such geographical indications; and

— Signs identical to or insignificantly different from another person's industrial design which has been protected on the basis of an application for registration of an industrial design with a filing date or priority date earlier than that of the application for registration of the mark.

Data protection

Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

— Patients have the right to have their health status and private information in their case history dossiers kept confidential.

— In general, such information can only be disclosed when agreed by patients, or for exchange of information and experience between practitioners directly treating the patients to improve the quality of diagnosis, care and treatment of patients, or in other cases provided by law.

— Persons who participate in a clinical trial have the right to have their relevant personal information kept secret (Article 57, Law on Pharmacy).

— A fine of VND10 million to VND20 million will apply for violations.

IP and competition law issues

What is the competition law framework and how does it impact on the Lifesciences sector?

Competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

— Competition cases now fall under the jurisdiction of the court and Inspectorate of the Ministry of Science and Technology.

— In the pharmaceutical sector, the issue of misleading trade indications stands out from other issues of competition.

— There have not been many cases of misleading indications recently.

— There have been no specific regulations on competition in licensing and technology transfer.

Competition issues associated with the generic entry of pharmaceuticals

— Vietnam has not laid down any specific regulations on competition law relating to patents. IP-related competition issues include the issues of misleading trade indication and cybersquatting only.

Abuse of dominance issues

— The issue has never arisen in the pharmaceutical field in Vietnam.

Parallel import issues

— Does not result in IP infringement or unfair competition.

Compulsory licence

— Although the regime of compulsory licensing is in place, the competent authorities have never granted such a licence.

How can LAN help?

Together, we can provide you with the best industry focused legal advice available in the APAC region. This is because we have:

Depth: more Lifesciences focused experts across key jurisdictions than any one firm.

Coverage: >2,500 lawyers operating from 25 offices in Australia, China, Hong Kong, India, Indonesia, Japan, Korea, Singapore, Taiwan, Thailand and Vietnam who understand the local culture and can provide local knowledge.

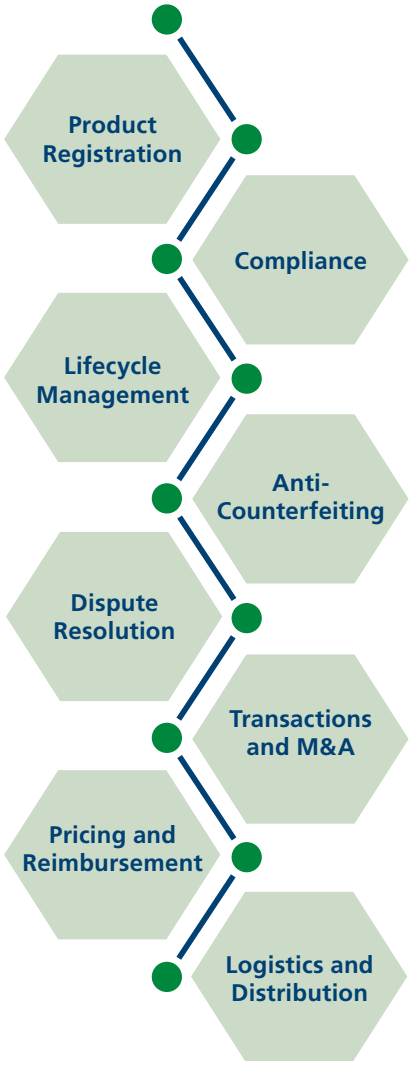
Technical experts: supported by numerous scientists, pharmacists and food technicians to provide specialist understanding.

Value for money: an ability to deliver expert and commercially focused advice at local and competitive rates.

Cross-border coordination: providing a one-stop shop for all your legal needs.

Powered by major international law firms: the network comprises some of the leading international law firms from the key 'pharmerging markets' in Asia-Pacific including Assegaf Hamzah & Partners, Atsumi & Sakai, Chen & Lin, CMS, Corrs Chambers Westgarth, Rajah & Tann Singapore LLP, Tilleke & Gibbins and Yulchon LLC.

Pan-regional services



Contact us

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Kate has worked on a number of high profile patent cases including the Australian case that clarified the law relating to patentability of methods of medical treatment. In addition to acting for pharmaceutical companies she has acted for many international clients in relation to medical devices including drug eluting stents, catheters and braces.

She has particular expertise in multi-jurisdictional litigation – recently she acted for Samsung in the smartphone litigation which was unprecedented in scale (23 patents were in suit).

Although Kate is foremost a litigator, she also has extensive experience in advertising and regulatory approvals and trade mark and contractual disputes in the pharmaceutical sector.

Kate was awarded the prestigious Euromoney Australasian Women in Business – 'IP rising star' award in 2013. She was also listed as a Best Lawyer for IP in the Best Lawyers Peer Reviews (2013–2016), as an IP star for trade mark and patent litigation in Managing Intellectual Property (2014–2016) and individually in the World Trade Mark Review.

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Nick is the Managing Partner of the Beijing Office, Global Co-Head of CMS Life Sciences & Healthcare Sector Group and Head of Asia-Pacific IP. Nick has extensive experience in advising on all aspects of intellectual property, regulatory and commercial matters affecting Life Sciences & Healthcare clients internationally and his practice spans both contentious and non-contentious issues.

Nick has substantial experience in coordinating complex multi-jurisdictional matters, regularly working with colleagues throughout CMS and around the world. His work in the areas of commercial and corporate transactions and disputes, parallel trade, anti-counterfeiting, trade mark and patent opinions and IP infringement particularly spans international borders.

Nick is recommended as a prominent practitioner in his field in Chambers & Partners, Legal 500, the PLC Lifesciences Handbook, Super Lawyers London, Who's Who Legal Trademarks and Life Sciences (Patent Litigation and Transactional) and the Guide to the World's Leading Trade Mark Law Practitioners. Nick was awarded 'Life Sciences Law – Lawyer of the Year in China' 2017 by Corporate Intl Magazine Global and Corporate LiveWire.

Nick is described as providing "heavyweight IP, parallel trade and patent litigation capability for an impressive roster of clients" and 'Dynamic' practice head Nick Beckett 'has an unparalleled ability to bring international teams together to deliver the precise expertise that his clients require'" in Legal 500. Nick is also described in Chambers & Partners for Lifesciences, "He has a really sophisticated understanding of life sciences in the Asia-Pacific region. He's very comfortable and savvy talking through the differences in jurisdictions and he has great commercial, regulatory and litigation expertise. He's just a delightful person, really generous and very inspired." Nick has also been recognised as a 'Top 15 IP Lawyer in China' by Asian Legal Business 2017.

Nick led the team on Takeda's €9.6bn acquisition of Swiss drug company, Nycomed A/S, which won the FT & Mergermarket Private Equity's Deal of the Year. In China, Nick's team has been ranked in the Asian Legal Business Asia's Top 50 Largest Law Firms (2014-2017) and been highly commended at the FT Innovative Lawyers for Asia-Pacific (2014-2017). In addition, the IP team in Asia is recognised in the Asian Legal Business IP Rankings.

Nick is a Solicitor-Advocate of the English Courts and a listed Arbitrator at the Beijing International Arbitration Centre (BIAC) and Beijing Arbitration Commission (BAC).

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Eko holds an LL.M. in banking and financial law from Boston University and has more than 15 years' experience as a legal practitioner. His focus extends across the corporate, banking & finance, and FDI practices, and he has amassed extensive experience in a range of rapidly expanding sectors, including Lifesciences, the creative industries and TMT.

He has advised a number of multinational companies on their FDI ventures in Indonesia, and is an Asialaw Profiles 'Recommended Lawyer.' His expertise was one of the contributing factors to Assegaf Hamzah being named an Asian-Mena Counsel 2014 'In-house Community Firm of the Year' in Indonesia for Lifesciences.

Prior to joining Assegaf Hamzah, Eko served as legal counsel with the Indonesian Bank Restructuring Agency (IBRA) during a tumultuous period that saw the agency rebuild the country's decimated financial services sector from the ruins of the 1997/98 Asian financial crisis. Eko speaks Indonesian and English.

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Chie, a Japanese-qualified attorney (Bengoshi) of some 15 years' standing, leads the IP/IT & Healthcare team. She is an IP/IT & Healthcare practitioner with deep knowledge of legal issues relevant to the life sciences field, and highly experienced in patent and regulatory/compliance matters. She represents biotechnology, medical device and other pharmaceutical companies in patent protection and litigation both domestic and cross-border. She also advises her clients on licensing, transfer, development and collaboration agreements.

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Ki Young is a co-chair of Yulchon's Healthcare Practice Team and a partner in the Corporate & Finance Group. After joining Yulchon in 1998, he successfully advised a number of international and Korean pharma/medical device companies on general corporate matters, including mergers and acquisitions, joint ventures and other strategic alliances, drug/medical device sales and distribution agreements, R&D related matters, and licensing and related disputes. Ki Young also specializes in government regulation and policy issues, including issues related to product approvals, market access, pricing, labeling, advertisement, healthcare insurance and regulation by the MOHW and the MFDS. Ki Young also provides extensive compliance and anti-corruption advice related to marketing activities to numerous international and Korean pharma/medical device companies.

Ki Young's experience includes a secondment with Allen & Overy, Hong Kong from 2003 to 2004 and service as an outside director of Ildong Pharmaceutical Co., Ltd. from 2010 to 2014. Currently, he serves as a legal adviser to the Korean Cosmetics Association, Korea Pharmaceutical Traders Association and Korea Medical Devices Industry Association, and he is an IRB member of St. Mary Hospital in Seoul.

Ki Young speaks English and Korean.

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Wee Hann has over 23 years of experience in advising companies on cross-border investments, private mergers & acquisitions, sale & purchase of companies and businesses and other corporate transactions. Wee Hann also specialises in labour law and employee benefits.

Wee Hann's expertise includes advising numerous biotechnology, health and pharmaceutical global leaders on cross-border acquisitions and divestments. He is a recommended lawyer in the PLC Lifesciences Handbook for his work in the Lifesciences industry and is also listed by the International Who's Who of Lifesciences Lawyers as one of the world's leading practitioners in the field of Lifesciences.

Wee Hann speaks English, Bahasa Malaysia, Mandarin, Vietnamese and is learning Japanese.

Taiwan

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Jennifer is the partner of Chen & Lin Attorneys-at-Law since 2008. Jennifer and Chen & Lin team have extensive experiences in serving clients in the sector of pharmaceuticals, biotech, medical device, nutritious food as well as cosmetics, including both domestic and international companies, hospitals, laboratories, associations and individuals.

Jennifer's specialised legal areas include foreign (PRC) investment, legal compliance, corporate, M&A, securities and anti-trust related issues. Jennifer, together with the team, provides holistic legal services to Lifesciences clients, ranging from administrative application, local legal compliance, fundraising, M&A, IPO, licensing, daily operation related agreements, patent litigation, maltreatment litigation and criminal procedures about health insurance fraud.

Jennifer is one of the ranked lawyers in Taiwan in Chambers & Partners Asia-Pacific 2018 in the fields of corporate/M&A and capital market.

Jennifer speaks Mandarin and English.

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Tilleke & Gibbins

Alan has over 15 years' experience in Asia, during which time he has devoted much of his work to IP acquisitions, strategic structuring, technology transfer, and IP licensing and securitisation agreements. He handles various IP infringement and regulatory infraction cases involving labelling, advertising, clinical trials, product handling/warehousing, product registration, taxation, and import/export violations in the Asia-Pacific region.

Alan focuses mainly on the pharmaceutical, agrochemical, and material science sectors. He also deals with local pre-litigation strategy and litigation management for infringement and invalidation matters in the region.

Alan represents diverse clients, from pioneers in Lifesciences to the biggest IP owners in the world, and he helps them achieve the dual goals of profit and protection. He has been recognised as one of the top 250 Lifesciences patent litigators in the world by Intellectual Asset Management, he was endorsed for his Lifesciences regulatory work by Practical Law Company, and he was identified as a leading Lifesciences regulatory lawyer by Who's Who Legal.

Alan speaks English and Mandarin.

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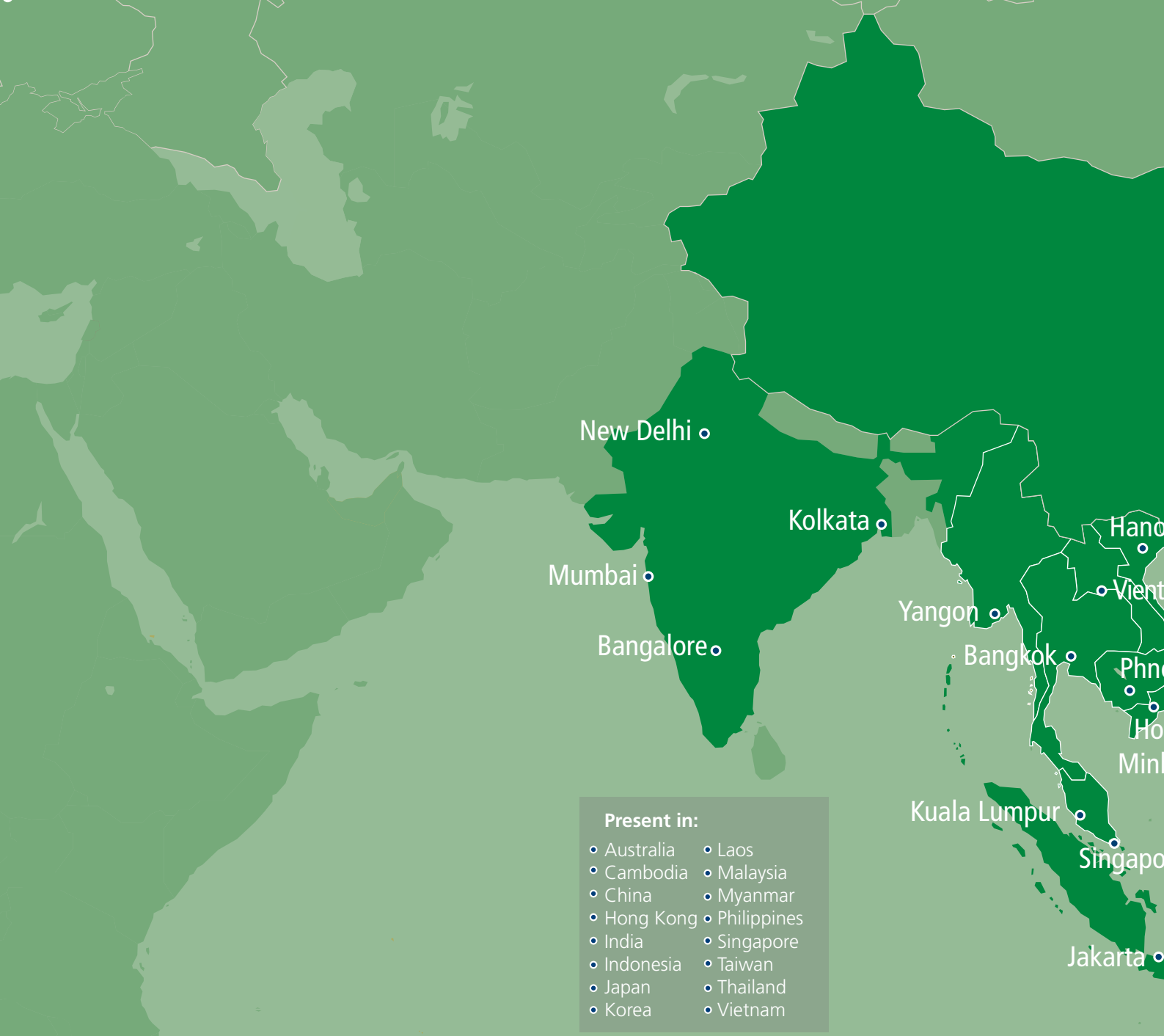
Tilleke & Gibbins

Tom is the Managing Director of Tilleke & Gibbins' Vietnam offices. He is an attorney licensed by the State Bar of California and is registered to practice as a foreign lawyer in Vietnam and before the USPTO and the U.S. Court of International Trade.

Tom has worked in the legal services field in Vietnam since 1994, specializing in corporate and commercial law as well as IP. Recognized as a leading lawyer by Chambers, The Legal 500, and Managing IP, Tom has extensive experience in IP enforcement and has secured a number of landmark victories for foreign investors operating in the Lifesciences and technology sectors.

Tom chairs the East Asia and Pacific Subcommittee of INTA's Famous and Well-Known Marks Committee; heads the Southeast Asia Subcommittee of AIPLA's IP Practice in the Far East Committee; and serves as the Chairman of AmCham Vietnam's IT, Telecom & IPR (ITTI) Committee. He is an advisor to EuroCham Vietnam's Pharma Group (an industry group of major pharmaceutical innovators), and has assisted with drafting position papers on compulsory licensing and a roadmap for Vietnam's compliance with the EU-Vietnam Free Trade Agreement and TRIPS.

Tom speaks English and Vietnamese.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Further information about each firm can be found respectively at www.ahp.co.id, www.aplaw.jp/en/, www.chenandlin.com, cms.law, www.corrs.com.au, www.rajahtann.com, www.tilleke.com, www.yulchon.com

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